

US3762023 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:40:55

All time stamps listed in this document are displayed in GMT

US3762023

Form: Participant Creation

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

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[Participant ID](#)

US3762023

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

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US3762023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3762023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3762023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

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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 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	1 UNK 2006
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 2006
Start Year (derived)	2006
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 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	TUBERCULOSIS
Start date (dd MMM yyyy)	1 UNK 1976
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)	31 UNK 1976
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 1976
Stop Year (derived)	1976

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	SPINAL LUMBAR ABSCESS
Start date (dd MMM yyyy)	1 UNK 2006
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)	31 UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	SHINGLES
Start date (dd MMM yyyy)	1 UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	31 UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	ARRHYTHMIA
Start date (dd MMM yyyy)	1 UNK 2014
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)	31 UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	AORTIC ANEURYSM
Start date (dd MMM yyyy)	01 UNK 2007
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)	31 UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	HERNIATED DISC
Start date (dd MMM yyyy)	01 UNK 2002
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)	31 UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	01 UNK 2006
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 2006
Start Year (derived)	2006
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 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	RAT POWDER ALLERGY
Start date (dd MMM yyyy)	01 UNK 1983
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	NEARSIGHTED
Start date (dd MMM yyyy)	01 UNK 1958
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 1958
Start Year (derived)	1958
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 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	TINNITUS
Start date (dd MMM yyyy)	01 UNK 1971
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 1971
Start Year (derived)	1971
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 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	HEARING LOSS
Start date (dd MMM yyyy)	01 UNK 1971
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 1971
Start Year (derived)	1971
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 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	MENIERE'S DISEASE
Start date (dd MMM yyyy)	01 UNK 1994
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)	01 UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	PARALYSIS
Start date (dd MMM yyyy)	01 UNK 2006
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)	01 UNK 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	BENIGN HYPERTROPHY PROSTATE
Start date (dd MMM yyyy)	01 UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Condition	DISCECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:57 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:57
Height ( <i>xxx.x</i> )	74 in
Weight ( <i>xxx.x</i> )	242 lb
BMI ( <i>xxx.x</i> )	31.13593 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

---

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 22:33:41

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 187598

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

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)	21 AUG 2020
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:57
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 16:45
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 16:05 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 16:05

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	15:41 (24 HR)
Collection date and time (derived)	21 AUG 2020 15:41

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:28	21 AUG 2020 15:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

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 09:40:55

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 16:39

PC Open Date & Time

21 AUG 2020 16:25

PC Close Date & Time

21 AUG 2020 18:55

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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 96.3 °F

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

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

PC Time Stamp	22 AUG 2020 07:07
PC Open Date & Time	21 AUG 2020 19:50
PC Close Date & Time	22 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 12:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 17:16

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 12:38

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 07:39

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 08:11

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 10:13

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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

21 AUG 2020 16:40

PC Open Date & Time

21 AUG 2020 16:25

PC Close Date & Time

21 AUG 2020 18:55

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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

22 AUG 2020 07:08

PC Open Date & Time

21 AUG 2020 19:50

PC Close Date & Time

22 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**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

22 AUG 2020 12:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**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

23 AUG 2020 17:17

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**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

24 AUG 2020 12:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**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

26 AUG 2020 07:40

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**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

27 AUG 2020 08:11

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**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

28 AUG 2020 10:14

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 16:41
PC Open Date & Time	21 AUG 2020 16:25
PC Close Date & Time	21 AUG 2020 18:55

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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 ☐



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Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 07:09
PC Open Date & Time	21 AUG 2020 19:50
PC Close Date & Time	22 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:02
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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 ☒

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 17:17
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:40
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 2139

EAB) (1725)



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 07:40
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 08:12
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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 ☒

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 10:14
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3762023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:32:58

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3762023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:32:58

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

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)	17 SEP 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 13:45
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 14:57
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3762023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 14:26 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 14:26

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



US3762023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

14:01 (24 HR)

Collection date and time (derived)

17 SEP 2020 14:01

US3762023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	17 SEP 2020 13:55
Nasopharyngeal Swab 2	No		

US3762023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 15:01

PC Open Date & Time

17 SEP 2020 14:46

PC Close Date & Time

17 SEP 2020 17:16

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 17 SEP 2020 18:11

PC Close Date & Time 18 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 17:26

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

19 SEP 2020 23:59

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

20 SEP 2020 22:18

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

22 SEP 2020 05:45

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

23 SEP 2020 09:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

24 SEP 2020 09:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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

17 SEP 2020 15:01

PC Open Date & Time

17 SEP 2020 14:46

PC Close Date & Time

17 SEP 2020 17:16

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 SEP 2020 18:11

PC Close Date & Time

18 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**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

18 SEP 2020 17:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**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

20 SEP 2020 00:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**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

20 SEP 2020 22:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**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

22 SEP 2020 05:46

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**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

23 SEP 2020 09:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**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

24 SEP 2020 09:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 15:01
PC Open Date & Time	17 SEP 2020 14:46
PC Close Date & Time	17 SEP 2020 17:16

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**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 ☐

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 18:11

PC Close Date & Time

18 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 17:28
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**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 ☒

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:19
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**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 ☒

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 05:46
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 09:36
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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 ☒

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 09:23
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3762023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments MISSED CALL

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3762023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:41

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:35 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 13:35
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	67 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

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.*

US3762023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	13:56 (24 HR)
Collection date and time (derived)	16 OCT 2020 13:56

US3762023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:33:42

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 12:00:59

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

31 OCT 2020 17:20:28

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59



US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

07 NOV 2020 06:28:29

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 07:16:28

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 08:04:02
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

02 DEC 2020 17:59:48

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

08 DEC 2020 12:01:03

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

13 DEC 2020 06:20:48

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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	20 DEC 2020 00:02:03
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

29 DEC 2020 12:00:36

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

03 JAN 2021 00:51:31

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 JAN 2021 07:42:51
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

17 JAN 2021 16:53:37

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

24 JAN 2021 15:33:29

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 JAN 2021 06:42:47
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

08 FEB 2021 06:54:30

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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	14 FEB 2021 07:41:13
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

21 FEB 2021 07:43:06

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

28 FEB 2021 16:33:40

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 MAR 2021 08:09:27
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

15 MAR 2021 17:05:42

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

24 MAR 2021 17:59:26

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

30 MAR 2021 14:33:57

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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

04 APR 2021 06:22:22

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 07:14:38

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 09:03:35

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:12:59

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 05:06:10

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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



US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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 <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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59

US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59
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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**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 ☐

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3762023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

US3762023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:40:55

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		27 FEB 2021 18:57:04

US3762023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 18:25:09

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 18:25:09

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3762023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 MAR 2021
Time of assessment (00:00-23:59)	08:32 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 08:32
Temperature (xxx.x)	97.7 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)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

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.*



US3762023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	8:39 (24 HR)
Collection date and time (derived)	8 MAR 2021 8:39

US3762023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 17:32:21

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 17:32:21

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3762023**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

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*

**US3762023**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3762023

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:40:55

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"/>

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3762023

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

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

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Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

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Folder OID	UNBLND_DECIDE
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US3762023

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Date of updated informed consent ( <i>dd MMM yyyy</i> )	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3762023

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Height	74 in
Weight	246 lb
BMI (xxx.x)	31.65057

US3762023

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Height	74 in
Weight	246 lb
BMI (xxx.x)	31.65057
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	08:11 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 08:11
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3762023

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Height	74 in
Weight	246 lb
BMI (xxx.x)	31.65057
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 09:27
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3762023

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

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3762023

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

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 08:57 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 08:57

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

US3762023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

08:15 (24 HR)

Collection date and time (derived)

11 JAN 2021 08:15



US3762023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	08:17
Collection Date and Time (derived)	11 JAN 2021 08:17

US3762023

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

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3762023

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	OLD29

US3762023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

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)	8 FEB 2021
Time of assessment (00:00-23:59)	08:17 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 08:17
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3762023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

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)	8 FEB 2021
Time of assessment (00:00-23:59)	09:29 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 09:29
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3762023

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 FEB 2021

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



US3762023

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 FEB 2021

What was the treatment time? (00:00-23:59) 08:57 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 08:57

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

US3762023

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 17:18:52

Generated On: 10 Jun 2021 09:40:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762023

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3762023

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:32 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 08:32
Temperature ( <i>xxx.x</i> )	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762023

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

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.*

US3762023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 MAR 2021
Collection time (00:00-23:59)	08:39 (24 HR)
Collection date and time (derived)	08 MAR 2021 08:39



US3762023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Mar 2021 17:23:37

Generated On: 10 Jun 2021 09:40:55

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 17:23:37

Generated On: 10 Jun 2021 09:40:55

AEID	USA-US130-2021-MRNA-1273-P30 1000004
Adverse event	AORTIC VALVE FAILURE
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)	26 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	26 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	30 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 17:23:37

Generated On: 10 Jun 2021 09:40:55

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

US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 17:23:37

Generated On: 10 Jun 2021 09:40:55

---

PATIENT PRESENTED WITH  
PMH WITH SIGNIFICANT  
REMOTE CARDIAC HISTORY TO  
INCLUDE S/P AORTIC ROOT  
REPLACEMENT AND AORTIC  
VALVE REPLACEMENT IN 2007,  
CARDIAC ABLATION FOR  
AVNRT IN 2014, REMOTE  
HISTORY OF BETA HEMOLYTIC  
STREP ENDOCARDITIS IN  
SETTING OF INFECTED MOLAR  
WHO PRESENTED TO WFBMC  
ED ON 01/26 FOR NEAR  
SYNCOPE. PATIENT STATES HE  
WAS RUNNING UP THE STAIRS  
AND FELT DISCOMFORT  
UNDER R CLAVICLE, WITHOUT  
CENTRAL CHEST PAIN OR  
RADIATION OF DISCOMFORT.  
PATIENT STARTED TO FEEL  
DIZZY, LIGHT HEADED, AND  
BEGAN TO LOSE PERIPHERAL  
VISION. PATIENT WAS ABLE TO  
MAKE IT TO HIS COUCH  
BEFORE PASSING OUT. PT  
STATES THIS HAS NEVER  
HAPPENED BEFORE. PATIENT  
EXTREMELY MEDICALLY  
LITERATE AND SHOWS  
EXCEPTIONAL INSIGHT TO  
SYMPTOMS. NO HISTORY OF  
IVDU. DENIES HA, CURRENT  
VISION CHANGES, ANGINA,  
PALPITATIONS, PLEURITIC  
CHEST PAIN, ABDOMINAL

US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 17:23:37

Generated On: 10 Jun 2021 09:40:55

---

PAIN, ABDOMINAL BLOATING,  
NAUSEA, VOMITING,  
DIARRHEA, CONSTIPATION,  
PERIPHERAL EDEMA, FEVER,  
CHILLS. ENDORSES DIZZINESS  
AND "FEELING DIFFERENT"  
THAN HIS BASELINE. NO COVID  
TESTING WAS PERFORMED  
PRIOR TO THIS PROCEDURE.

---

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

---

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

---

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

Yes ☒

No ☐

---

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

---

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication METOPROLOL

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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US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication HCT HYDROCLYOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (3)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 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"/>

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication LOVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 UNK 2006	
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"/>

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT FOR HEART  
HEALTH

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	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)	01 UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 UNK 2006	
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"/>

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

	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)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication PLAVIX

Prophylaxis Yes ☐  
No ☒

Indication AORTIC ANEURYSM

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

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

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication AORTIC VALVE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

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



US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 17:16:20

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 JAN 2021	CT ANGIOGRAPHY OF THE HEART	Adverse Event	

US3762023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:40:55

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3762023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:40:55

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 ☐

US3762023

Folder: SAE USA-US130-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US130-2021-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3762023

Folder: SAE USA-US130-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US130-2021-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/FEB/2021 15:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762023

Folder: SAE USA-US130-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 17:18:51

Generated On: 10 Jun 2021 09:40:55

SAEID	USA-US130-2021-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/FEB/2021 15:59
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

US3762023 (Prod: Wake Forest University Health Sciences)



**US3762023**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:40:55**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered 'US3762023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:54:46

**US3762023**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:15:57

**US3762023**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:54:48

US3762023

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

[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 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Clinic (Clinic)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:15:57

**US3762023**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'SCRN'	System	21 Aug 2020 20:15:57

US3762023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:54:49

US3762023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	24 Aug 2020 19:35:02
User entered '66' reason for change: Data Entry Error	Chie Hooker (b) (4)	24 Aug 2020 19:35:02
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 19:34:55
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 19:34:55
User entered '67' reason for change: Data Entry Error	Chie Hooker (b) (4)	24 Aug 2020 19:34:55
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 19:34:24
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 19:34:24
User entered '75' reason for change: Data Entry Error	Chie Hooker (b) (4)	24 Aug 2020 19:34:24
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	24 Aug 2020 19:34:01
User entered '76'	Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'YEARS'	System	24 Aug 2020 19:34:01



**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '66'	System	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Male (M)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

US3762023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'I'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

US3762023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:40:55

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01



**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:40:55**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:34:01

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Aug 2020'	System	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2020'	System	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Amendment 2 (2)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:15



**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:15

US3762023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:40:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:15

**US3762023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:40:55**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:54:48

US3762023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:40:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'I'	System	21 Aug 2020 20:16:22

US3762023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:40:55

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4)	21 Aug 2020 20:16:22

US3762023

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:40:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:35:33



US3762023

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:39:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:39:43
Data point term sent to Coder	System	24 Aug 2020 19:38:20
User entered 'High Blood Pressure'	Chie Hooker (b) (4)	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '1 UNK 2006' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 17:24:36
User entered '1 UNK 2007' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 14:58:19
User entered '1 UNK 2006'	Chie Hooker (b) (4)	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2006'	System	25 Jan 2021 17:24:36
User entered 'Jan 2007'	System	10 Dec 2020 14:58:19
User entered 'Jan 2006'	System	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2006'	System	25 Jan 2021 17:24:36
User entered '2007'	System	10 Dec 2020 14:58:19
User entered '2006'	System	24 Aug 2020 19:37:53



**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	24 Aug 2020 19:37:53

**US3762023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	24 Aug 2020 19:37:53

US3762023

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Infections and infestations, HLGT: Mycobacterial infectious disorders, HLT: Tuberculous infections, PT: Tuberculosis, LLT: Tuberculosis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:40:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:40:47
Data point term sent to Coder	System	24 Aug 2020 19:39:22
User entered 'Tuberculosis'	Chie Hooker (b) (4)	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '1 UNK 1976'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '31 UNK 1976'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:38:52



**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1976'	System	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1976'	System	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1976'	System	24 Aug 2020 19:38:52

**US3762023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1976'	System	24 Aug 2020 19:38:52

US3762023

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Central nervous system and spinal infections, PT: Spinal cord abscess, LLT: Spinal cord abscess - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:20:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:20:41
Data point term sent to Coder	System	24 Aug 2020 19:40:29
User entered 'Spinal Lumbar Abscess'	Chie Hooker (b) (4)	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '1 UNK 2006'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:40:28



**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '31 UNK 2006'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2006'	System	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2006'	System	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2006'	System	24 Aug 2020 19:40:28

**US3762023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2006'	System	24 Aug 2020 19:40:28

US3762023

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:42:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:42:48
Data point term sent to Coder	System	24 Aug 2020 19:41:30
User entered 'Shingles'	Chie Hooker (b) (4)	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '1 UNK 1998'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:41:25



**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '31 UNK 1998'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1998'	System	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1998'	System	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1998'	System	24 Aug 2020 19:41:25

**US3762023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1998'	System	24 Aug 2020 19:41:25



US3762023

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:44:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:44:43
Data point term sent to Coder	System	24 Aug 2020 19:43:38
User entered 'Arrhythmia'	Chie Hooker (b) (4)	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '1 UNK 2014'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '31 UNK 2014'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2014'	System	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2014'	System	24 Aug 2020 19:43:30



**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2014'	System	24 Aug 2020 19:43:30

**US3762023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2014'	System	24 Aug 2020 19:43:30

US3762023

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Aortic aneurysm - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:45:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:45:46
Data point term sent to Coder	System	24 Aug 2020 19:44:42
User entered 'Aortic Aneurysm'	Chie Hooker (b) (4)	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 2007'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '31 UNK 2007'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:44:37



**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2007'	System	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2007'	System	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2007'	System	24 Aug 2020 19:44:37

**US3762023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2007'	System	24 Aug 2020 19:44:37

US3762023

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:06:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:06:00
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) HERNIATED DISC 2) DISCECTOMY' (Site from System).	System	20 Oct 2020 19:04:13
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) HERNIATED DISC 2) DISCECTOMY' answered with 'updated' (Site from System).	Samantha Wheeler (b) (4)	20 Oct 2020 19:04:13
Data point term sent to Coder	System	20 Oct 2020 19:03:49
Coding entries removed.	Samantha Wheeler (b) (4)	20 Oct 2020 19:03:38
User entered 'HERNIATED DISC' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	20 Oct 2020 19:03:38
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) HERNIATED DISC 2) DISCECTOMY' (Site from System).	Coder Import (b) (4)	02 Oct 2020 15:32:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:38:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 20:38:47
Data point term sent to Coder	System	24 Aug 2020 19:46:50

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition](#)

Audit	User	Time (GMT)
User entered 'Herniated disc/Discectomy'	Chie Hooker (b) (4) [REDACTED]	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 2002'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:46:41



**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '31 UNK 2002'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2002'	System	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2002'	System	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2002'	System	24 Aug 2020 19:46:41

**US3762023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2002'	System	24 Aug 2020 19:46:41

US3762023

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:49:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:49:36
Data point term sent to Coder	System	24 Aug 2020 19:48:51
User entered 'High Cholesterol'	Chie Hooker (b) (4)	24 Aug 2020 19:48:04



**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 2006'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:48:04

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:48:04

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 17:22:54
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	24 Aug 2020 19:48:04
	Chie Hooker (b) (4)	

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty; reason for change Data Entry Error	(b) (4)	25 Jan 2021 17:22:54
User entered '31 UNK 2006'	Kaitlyn Van Leuvan (b) (4)	24 Aug 2020 19:48:04
	Chie Hooker (b) (4)	

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:48:04

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2006'	System	24 Aug 2020 19:48:04

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2006'	System	24 Aug 2020 19:48:04

**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	25 Jan 2021 17:22:54
User entered 'Jan 2006'	System	24 Aug 2020 19:48:04



**US3762023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	25 Jan 2021 17:22:54
User entered '2006'	System	24 Aug 2020 19:48:04

US3762023

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to chemicals, LLT: Allergy to chemicals - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 11:32:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 11:32:56
Data point term sent to Coder	System	26 Aug 2020 14:15:42
User entered 'Rat Powder allergy'	(b) (4), (b) (6)	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 1983'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1983'	System	26 Aug 2020 14:15:15



**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1983'	System	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:15:15

**US3762023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:15:15

US3762023

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 21:20:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 21:20:50
Data point term sent to Coder	System	21 Sep 2020 21:19:19
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	21 Sep 2020 21:19:15
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'done' (Site from System).	Amanda Wright (b) (4)	21 Sep 2020 21:19:15
User entered 'NEARSIGHTED' reason for change: Data Entry Error	Amanda Wright (b) (4)	21 Sep 2020 21:19:09
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	27 Aug 2020 22:54:44
Data point term sent to Coder	System	26 Aug 2020 14:16:43
User entered 'Farsighted/Nearsighted'	(b) (4), (b) (6)	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 1958'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:16:16



**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1958'	System	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1958'	System	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:16:16

**US3762023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:16:16

US3762023

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:52:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:52:50
Data point term sent to Coder	System	10 Dec 2020 14:51:45
Coding entries removed.	(b) (4), (b) (6)	10 Dec 2020 14:51:23
User entered 'TINNITUS' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 14:51:23
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:37:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:37:52
Data point term sent to Coder	System	26 Aug 2020 14:17:47
User entered 'Tinnitus'	(b) (4), (b) (6)	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 1971' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:23
User entered '01 UNK 1991'	(b) (4), (b) (6)	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:17:18



**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1971'	System	10 Dec 2020 14:51:23
User entered 'Jan 1991'	System	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1971'	System	10 Dec 2020 14:51:23
User entered '1991'	System	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:17:18

**US3762023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:17:18

US3762023

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:19:48
Data point term sent to Coder	System	26 Aug 2020 14:18:51
User entered 'Hearing loss'	(b) (4), (b) (6)	26 Aug 2020 14:18:01



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**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 1971'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1971'	System	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1971'	System	26 Aug 2020 14:18:01

**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:18:01



**US3762023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:18:01

US3762023

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:40:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear disorders NEC, PT: Meniere's disease, LLT: Meniere's disease - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:19:48
Data point term sent to Coder	System	26 Aug 2020 14:18:53
User entered 'Meniere's Disease'	(b) (4), (b) (6)	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 1994'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 1994'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1994'	System	26 Aug 2020 14:18:44



**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1994'	System	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 1994'	System	26 Aug 2020 14:18:44

**US3762023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1994'	System	26 Aug 2020 14:18:44

US3762023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Paralysis and paresis (excl cranial nerve), PT: Paralysis, LLT: Paralysis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:22:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Aug 2020 14:22:52
Data point term sent to Coder	System	26 Aug 2020 14:22:00
User entered 'Paralysis'	(b) (4), (b) (6)	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 2006'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 2006'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:21:16



**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2006'	System	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2006'	System	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2006'	System	26 Aug 2020 14:21:16

**US3762023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2006'	System	26 Aug 2020 14:21:16

US3762023

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Per MM, please review and update the term to reflect the final diagnosis' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 11:11:56
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:07:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 19:07:36
Data point term sent to Coder	System	20 Oct 2020 19:07:01
Query 'Per MM, please review and update the term to reflect the final diagnosis' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:06:14
Coding entries removed.	Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:06:10
User entered 'benign hypertrophy prostate' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:06:10
User opened query 'Per MM, please review and update the term to reflect the final diagnosis' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 03:14:54
User coded data point as SOC: Investigations, HLGT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen normal, LLT: PSA normal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 07:40:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 07:40:38
Data point term sent to Coder	System	26 Aug 2020 14:24:07
User entered 'Genitourinary - Other BP4 (PSA Normal)'	(b) (4), (b) (6)	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '01 UNK 2015'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:23:17



**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2015'	System	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2015'	System	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:23:17

**US3762023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered empty.	System	26 Aug 2020 14:23:17

US3762023

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:40:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Discectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:06:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 19:06:01
Data point term sent to Coder	System	20 Oct 2020 19:04:55
User entered 'discectomy'	Samantha Wheeler (b) (4)	20 Oct 2020 19:03:54



**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'un UNK 2002'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4)	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'un UNK 2002'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2002'	System	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2002'	System	20 Oct 2020 19:03:54

**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'Jan 2002'	System	20 Oct 2020 19:03:54



**US3762023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:40:55**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '2002'	System	20 Oct 2020 19:03:54

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '14:57' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered '14:22'	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '21 Aug 2020 14:57'	System	26 Aug 2020 14:32:57
User entered '21 Aug 2020 14:22'	System	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '74' in	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:49:28
DataPoint set to visible.	System	21 Aug 2020 20:16:22

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '242' lb	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:49:28
DataPoint set to visible.	System	21 Aug 2020 20:16:22

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
Amendment Manager: User entered '31.13593'	System	17 Sep 2020 00:19:02
User entered '31.1'	System	24 Aug 2020 19:49:28
DataPoint set to visible.	System	21 Aug 2020 20:16:22



**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'kg/m2'	System	24 Aug 2020 19:49:28
DataPoint set to visible.	System	21 Aug 2020 20:16:22

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered '98.4' F	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Per CDM: Please note that Route of Measurement is not expected to be entered when Temperature is Not Done. Kindly consider to remove "Other" in this field as well as "ND" in If Other, specify field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:55:37
Query 'Per CDM: Please note that Route of Measurement is not expected to be entered when Temperature is Not Done. Kindly consider to remove "Other" in this field as well as "ND" in If Other, specify field. ' answered with 'done' (Site from DM).	James Lovette (b) (4) (b) (4)	28 Sep 2020 14:26:22
User entered empty; reason for change Data Entry Error	James Lovette (b) (4) (b) (4)	28 Sep 2020 14:26:09
User opened query 'Per CDM: Please note that Route of Measurement is not expected to be entered when Temperature is Not Done. Kindly consider to remove "Other" in this field as well as "ND" in If Other, specify field. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:20:28
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered 'Oral (Oral)'	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty; reason for change Data Entry Error	(b) (4)	
	James Lovette (b) (4)	28 Sep 2020 14:26:34
User entered 'Not Done' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered empty.	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered '80'	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'bpm'	System	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered '18'	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'breaths/min'	System	24 Aug 2020 19:49:28



US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered '142'	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mmHg'	System	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:32:57
User entered '99'	Chie Hooker (b) (4)	24 Aug 2020 19:49:28

**US3762023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mmHg'	System	24 Aug 2020 19:49:28

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43

US3762023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43

US3762023

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:49:37

**US3762023**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 19:49:37



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**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03



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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	(b) (4)	26 Aug 2020 14:34:50
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	24 Aug 2020 20:24:03
User entered 'I'	Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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Folder: Screening

Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03



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Folder: Screening

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:34:50
User entered '1'	Chie Hooker (b) (4)	24 Aug 2020 20:24:03

**US3762023**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:40:55**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '0'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:40:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:24:03

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:42

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Samantha Wheeler (b) (4)	21 Aug 2020 20:16:42

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Clinic (Clinic)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:16:42



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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'VISIT1'	System	21 Aug 2020 20:16:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:20:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '187598'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:20:35

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:20:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:17:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:40:55

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:17:37

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:17:37

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:17:37



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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:17:37

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:40:55**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4)	
	Samantha Wheeler (b) (4)	25 Oct 2020 19:53:43
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:35:58
User entered '74' in	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:35:58
User entered '242' lb	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:35:58
User entered '74' in	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:40:55**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:35:58
User entered '242' lb	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Pre-Dose (PREDOSE)'	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '14:57' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:36:27
User entered '14:22'	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '21 Aug 2020 14:57'	System	26 Aug 2020 14:36:27
User entered '21 Aug 2020 14:22'	System	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '98.4' F	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Oral (Oral)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '80'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'bpm'	System	24 Aug 2020 20:26:52



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '18'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'breaths/min'	System	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '142'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '99'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:35:58
User entered '74' in	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 14:35:58
User entered '242' lb	Chie Hooker (b) (4)	24 Aug 2020 20:26:52



US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Post-Dose (POSTDOSE)'	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '16:45' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:37:40
User entered '16:35'	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '21 Aug 2020 16:45'	System	26 Aug 2020 14:37:40
User entered '21 Aug 2020 16:35'	System	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '96.8' F	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Oral (Oral)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52



US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '75'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'bpm'	System	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '20'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'breaths/min'	System	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:52:53
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject had no symptoms at time BP was recorded' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 14:37:36
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Aug 2020 20:26:52
User entered '167'	Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '98'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:26:52

US3762023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	24 Aug 2020 20:26:52



US3762023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:35:24
User entered 'Yes (Y)'	Chie Hooker (b) (4)	24 Aug 2020 20:27:17

US3762023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:35:24
User entered '21 Aug 2020'	Chie Hooker (b) (4)	24 Aug 2020 20:27:17

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:18:34

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4)	
	Samantha Wheeler (b) (4)	21 Aug 2020 20:18:34
	(b) (4)	

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:18:34

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 20:18:34

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Samantha Wheeler (b) (4)	21 Aug 2020 20:18:34
	(b) (4)	

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '16:05'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:18:34



**US3762023**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '21 Aug 2020 16:05'	System	21 Aug 2020 20:18:34

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Aug 2020 20:18:34

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'ONCE'	System	21 Aug 2020 20:18:34

US3762023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 20:18:34

US3762023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:27:58

US3762023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:27:58

US3762023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '15:41'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:27:58

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '21 Aug 2020 15:41'	System	24 Aug 2020 20:27:58



US3762023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:40:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '21 Aug 2020'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:28:17

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chie Hooker (b) (4)	24 Aug 2020 20:28:17

US3762023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:28:17

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '15:28'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:28:17

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '21 Aug 2020 15:28'	System	24 Aug 2020 20:28:17

US3762023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:40:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chie Hooker (b) (4)	24 Aug 2020 20:28:17

US3762023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:28:17

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:28:17



**US3762023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered empty.	System	24 Aug 2020 20:28:17

US3762023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) Chie Hooker (b) (4)	24 Aug 2020 20:28:22

**US3762023**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	24 Aug 2020 20:28:22

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:39:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b7bf898f-ad33-47c4-9dbb-754b8e341781' User entered 'Yes (Y)'	System	21 Aug 2020 20:39:45
	System	21 Aug 2020 20:39:45

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:39:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b7bf898f-ad33-47c4-9dbb-754b8e341781' User entered '96.8'	System	21 Aug 2020 20:39:45
	System	21 Aug 2020 20:39:45

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:39:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b7bf898f-ad33-47c4-9dbb-754b8e341781'	System	21 Aug 2020 20:39:45
User entered 'No (N)'	System	21 Aug 2020 20:39:45

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:39:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b7bf898f-ad33-47c4-9dbb-754b8e341781' User entered '21 Aug 2020 16:39'	System	21 Aug 2020 20:39:45
	System	21 Aug 2020 20:39:45



US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 16:25'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 18:55'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:07:23', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '84740e53-c81a-424b-a91c-7bd3a0e65ef5' User entered 'Yes (Y)'	System	22 Aug 2020 11:07:52
	System	22 Aug 2020 11:07:52

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:07:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '84740e53-c81a-424b-a91c-7bd3a0e65ef5' User entered '96.3'	System	22 Aug 2020 11:07:52
	System	22 Aug 2020 11:07:52

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:07:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '84740e53-c81a-424b-a91c-7bd3a0e65ef5'	System	22 Aug 2020 11:07:52
User entered 'No (N)'	System	22 Aug 2020 11:07:52

**US3762023**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:07:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '84740e53-c81a-424b-a91c-7bd3a0e65ef5' User entered '22 Aug 2020 07:07'	System	22 Aug 2020 11:07:52
	System	22 Aug 2020 11:07:52

**US3762023**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 19:50'	System	21 Aug 2020 20:18:34



**US3762023**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 2'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:00:57', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f9eb6958-d583-44d3-a771-60720918b5ba' User entered 'Yes (Y)'	System	22 Aug 2020 16:01:15
	System	22 Aug 2020 16:01:15

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:04', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f9eb6958-d583-44d3-a771-60720918b5ba' User entered '96.3'	System	22 Aug 2020 16:01:15
	System	22 Aug 2020 16:01:15

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:08', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f9eb6958-d583-44d3-a771-60720918b5ba' User entered 'No (N)'	System	22 Aug 2020 16:01:15
	System	22 Aug 2020 16:01:15

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:13', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f9eb6958-d583-44d3-a771-60720918b5ba' User entered '22 Aug 2020 12:01'	System	22 Aug 2020 16:01:15
	System	22 Aug 2020 16:01:15

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 20:18:34



US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 3'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:16:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '19898996-b79f-46fb-a6b6-ef129cf683de' User entered 'Yes (Y)'	System	23 Aug 2020 21:16:47
	System	23 Aug 2020 21:16:47

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:16:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '19898996-b79f-46fb-a6b6-ef129cf683de' User entered '98.6'	System	23 Aug 2020 21:16:47
	System	23 Aug 2020 21:16:47

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:16:38', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '19898996-b79f-46fb-a6b6-ef129cf683de' User entered 'No (N)'	System	23 Aug 2020 21:16:47
	System	23 Aug 2020 21:16:47

**US3762023**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:16:45', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '19898996-b79f-46fb-a6b6-ef129cf683de' User entered '23 Aug 2020 17:16'	System	23 Aug 2020 21:16:47
	System	23 Aug 2020 21:16:47

**US3762023**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 4'	System	21 Aug 2020 20:18:34



US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:38:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7eb19b6e-8850-4c05-97ed-282dfa5c9ab9' User entered 'Yes (Y)'	System	24 Aug 2020 16:38:47
	System	24 Aug 2020 16:38:47

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:38:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7eb19b6e-8850-4c05-97ed-282dfa5c9ab9' User entered '97.4'	System	24 Aug 2020 16:38:47
	System	24 Aug 2020 16:38:47

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:38:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7eb19b6e-8850-4c05-97ed-282dfa5c9ab9' User entered 'No (N)'	System	24 Aug 2020 16:38:47
	System	24 Aug 2020 16:38:47

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:38:46', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7eb19b6e-8850-4c05-97ed-282dfa5c9ab9'	System	24 Aug 2020 16:38:47
User entered '24 Aug 2020 12:38'	System	24 Aug 2020 16:38:47

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 5'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:39:41', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2955e52-e595-495f-a5ed-75b79117a72e' User entered 'Yes (Y)'	System	26 Aug 2020 11:40:01
	System	26 Aug 2020 11:40:01



US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:39:51', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2955e52-e595-495f-a5ed-75b79117a72e' User entered '98.2'	System	26 Aug 2020 11:40:01
	System	26 Aug 2020 11:40:01

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:39:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2955e52-e595-495f-a5ed-75b79117a72e' User entered 'No (N)'	System	26 Aug 2020 11:40:01
	System	26 Aug 2020 11:40:01

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:39:59', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2955e52-e595-495f-a5ed-75b79117a72e' User entered '26 Aug 2020 07:39'	System	26 Aug 2020 11:40:01
	System	26 Aug 2020 11:40:01

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 6'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:19', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '05e9eea3-6cac-45f2-8c56-c1306ac01a53'	System	27 Aug 2020 12:11:36
User entered 'Yes (Y)'	System	27 Aug 2020 12:11:36

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '05e9eea3-6cac-45f2-8c56-c1306ac01a53' User entered '97.6'	System	27 Aug 2020 12:11:36
	System	27 Aug 2020 12:11:36



US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '05e9eea3-6cac-45f2-8c56-c1306ac01a53'	System	27 Aug 2020 12:11:36
User entered 'No (N)'	System	27 Aug 2020 12:11:36

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '05e9eea3-6cac-45f2-8c56-c1306ac01a53' User entered '27 Aug 2020 08:11'	System	27 Aug 2020 12:11:36
	System	27 Aug 2020 12:11:36

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 7'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:12:54', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a1faf1f1-f3eb-448e-827d-632249766302' User entered 'Yes (Y)'	System	28 Aug 2020 14:13:44
	System	28 Aug 2020 14:13:44

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:13:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a1faf1f1-f3eb-448e-827d-632249766302' User entered '98.1'	System	28 Aug 2020 14:13:44
	System	28 Aug 2020 14:13:44

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:13:33', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a1faf1f1-f3eb-448e-827d-632249766302'	System	28 Aug 2020 14:13:44
User entered 'No (N)'	System	28 Aug 2020 14:13:44



**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:13:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a1faf1f1-f3eb-448e-827d-632249766302' User entered '28 Aug 2020 10:13'	System	28 Aug 2020 14:13:44
	System	28 Aug 2020 14:13:44

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:39:58', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7af0550e-5642-4cbf-b69a-e61ba44afdad' User entered 'None (1)'	System	21 Aug 2020 20:40:43
	System	21 Aug 2020 20:40:43

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:18', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7af0550e-5642-4cbf-b69a-e61ba44afdad' User entered 'No (N)'	System	21 Aug 2020 20:40:43
	System	21 Aug 2020 20:40:43

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7af0550e-5642-4cbf-b69a-e61ba44afdad' User entered 'No (N)'	System	21 Aug 2020 20:40:43
	System	21 Aug 2020 20:40:43

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7af0550e-5642-4cbf-b69a-e61ba44afdad' User entered 'None (1)'	System	21 Aug 2020 20:40:43
	System	21 Aug 2020 20:40:43



**US3762023**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:41', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '7af0550e-5642-4cbf-b69a-e61ba44afdad' User entered '21 Aug 2020 16:40'	System	21 Aug 2020 20:40:43
	System	21 Aug 2020 20:40:43

**US3762023**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 16:25'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 18:55'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:07:55', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e94d136c-8307-4dbe-935a-931573f3d474' User entered 'None (1)'	System	22 Aug 2020 11:08:24
	System	22 Aug 2020 11:08:24

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:07:59', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e94d136c-8307-4dbe-935a-931573f3d474' User entered 'No (N)'	System	22 Aug 2020 11:08:24
	System	22 Aug 2020 11:08:24

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e94d136c-8307-4dbe-935a-931573f3d474' User entered 'No (N)'	System	22 Aug 2020 11:08:24
	System	22 Aug 2020 11:08:24

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:19', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e94d136c-8307-4dbe-935a-931573f3d474' User entered 'None (1)'	System	22 Aug 2020 11:08:24
	System	22 Aug 2020 11:08:24



**US3762023**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:23', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e94d136c-8307-4dbe-935a-931573f3d474' User entered '22 Aug 2020 07:08'	System	22 Aug 2020 11:08:24
	System	22 Aug 2020 11:08:24

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 19:50'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 2'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:18', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '10556468-1497-42c8-919f-7c8c18cf1bf8'	System	22 Aug 2020 16:01:43
User entered 'None (1)'	System	22 Aug 2020 16:01:43

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '10556468-1497-42c8-919f-7c8c18cf1bf8'	System	22 Aug 2020 16:01:43
User entered 'No (N)'	System	22 Aug 2020 16:01:43

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '10556468-1497-42c8-919f-7c8c18cf1bf8'	System	22 Aug 2020 16:01:43
User entered 'No (N)'	System	22 Aug 2020 16:01:43

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '10556468-1497-42c8-919f-7c8c18cf1bf8'	System	22 Aug 2020 16:01:43
User entered 'None (1)'	System	22 Aug 2020 16:01:43



**US3762023**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '10556468-1497-42c8-919f-7c8c18cf1bf8' User entered '22 Aug 2020 12:01'	System	22 Aug 2020 16:01:43
	System	22 Aug 2020 16:01:43

**US3762023**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 3'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:16:50', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '34823180-d2f9-491c-97fe-ebca2a68c63d' User entered 'None (1)'	System	23 Aug 2020 21:17:17
	System	23 Aug 2020 21:17:17

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '34823180-d2f9-491c-97fe-ebca2a68c63d' User entered 'No (N)'	System	23 Aug 2020 21:17:17
	System	23 Aug 2020 21:17:17

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:07', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '34823180-d2f9-491c-97fe-ebca2a68c63d' User entered 'No (N)'	System	23 Aug 2020 21:17:17
	System	23 Aug 2020 21:17:17

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:10', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '34823180-d2f9-491c-97fe-ebca2a68c63d' User entered 'None (1)'	System	23 Aug 2020 21:17:17
	System	23 Aug 2020 21:17:17



**US3762023**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:16', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '34823180-d2f9-491c-97fe-ebca2a68c63d' User entered '23 Aug 2020 17:17'	System	23 Aug 2020 21:17:17
	System	23 Aug 2020 21:17:17

**US3762023**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 4'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:39:59', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fef9003e-14ad-4277-b258-75f5f04b4026'	System	24 Aug 2020 16:40:25
User entered 'None (1)'	System	24 Aug 2020 16:40:25

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:02', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fef9003e-14ad-4277-b258-75f5f04b4026'	System	24 Aug 2020 16:40:25
User entered 'No (N)'	System	24 Aug 2020 16:40:25

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fef9003e-14ad-4277-b258-75f5f04b4026'	System	24 Aug 2020 16:40:25
User entered 'No (N)'	System	24 Aug 2020 16:40:25

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:15', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fef9003e-14ad-4277-b258-75f5f04b4026'	System	24 Aug 2020 16:40:25
User entered 'None (1)'	System	24 Aug 2020 16:40:25



US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fef9003e-14ad-4277-b258-75f5f04b4026'	System	24 Aug 2020 16:40:25
User entered '24 Aug 2020 12:40'	System	24 Aug 2020 16:40:25

**US3762023**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 5'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2ef29e95-990e-4917-98e2-10a13ced0832'	System	26 Aug 2020 11:40:23
User entered 'None (1)'	System	26 Aug 2020 11:40:23

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:09', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2ef29e95-990e-4917-98e2-10a13ced0832' User entered 'No (N)'	System	26 Aug 2020 11:40:23
	System	26 Aug 2020 11:40:23

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:12', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2ef29e95-990e-4917-98e2-10a13ced0832' User entered 'No (N)'	System	26 Aug 2020 11:40:23
	System	26 Aug 2020 11:40:23

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:15', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2ef29e95-990e-4917-98e2-10a13ced0832' User entered 'None (1)'	System	26 Aug 2020 11:40:23
	System	26 Aug 2020 11:40:23



**US3762023**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:21', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2ef29e95-990e-4917-98e2-10a13ced0832' User entered '26 Aug 2020 07:40'	System	26 Aug 2020 11:40:23
	System	26 Aug 2020 11:40:23

**US3762023**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 6'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f54c16be-e1cb-43e4-a021-ca03bdd0a3c1' User entered 'None (1)'	System	27 Aug 2020 12:11:58
	System	27 Aug 2020 12:11:58

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f54c16be-e1cb-43e4-a021-ca03bdd0a3c1' User entered 'No (N)'	System	27 Aug 2020 12:11:58
	System	27 Aug 2020 12:11:58

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:46', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f54c16be-e1cb-43e4-a021-ca03bdd0a3c1' User entered 'No (N)'	System	27 Aug 2020 12:11:58
	System	27 Aug 2020 12:11:58

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:51', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f54c16be-e1cb-43e4-a021-ca03bdd0a3c1' User entered 'None (1)'	System	27 Aug 2020 12:11:58
	System	27 Aug 2020 12:11:58



**US3762023**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:11:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f54c16be-e1cb-43e4-a021-ca03bdd0a3c1' User entered '27 Aug 2020 08:11'	System	27 Aug 2020 12:11:58
	System	27 Aug 2020 12:11:58

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 7'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:13:49', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8464ac7e-cea8-4e9c-9d20-0a4de79bbd7a' User entered 'None (1)'	System	28 Aug 2020 14:14:08
	System	28 Aug 2020 14:14:08

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:13:53', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8464ac7e-cea8-4e9c-9d20-0a4de79bbd7a' User entered 'No (N)'	System	28 Aug 2020 14:14:08
	System	28 Aug 2020 14:14:08

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:13:57', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8464ac7e-cea8-4e9c-9d20-0a4de79bbd7a' User entered 'No (N)'	System	28 Aug 2020 14:14:08
	System	28 Aug 2020 14:14:08

US3762023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8464ac7e-cea8-4e9c-9d20-0a4de79bbd7a' User entered 'None (1)'	System	28 Aug 2020 14:14:08
	System	28 Aug 2020 14:14:08



**US3762023**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:05', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8464ac7e-cea8-4e9c-9d20-0a4de79bbd7a' User entered '28 Aug 2020 10:14'	System	28 Aug 2020 14:14:08
	System	28 Aug 2020 14:14:08

**US3762023**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:50', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'None (0)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:53', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'None (0)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:40:57', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'None (0)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:41:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'None (0)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18



**US3762023**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:41:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'None (0)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:41:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'None (0)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:41:14', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered 'No (N)'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

**US3762023**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-21T16:41:16', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cadb2d17-b0ec-465e-9065-39ae4e1d449b' User entered '21 Aug 2020 16:41'	System	21 Aug 2020 20:41:18
	System	21 Aug 2020 20:41:18

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 16:25'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 18:55'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'None (0)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'None (0)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'None (0)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:44', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'None (0)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:47', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'None (0)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:49', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'None (0)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:08:55', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered 'No (N)'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

**US3762023**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T07:09:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b1ac9640-cb95-49f4-bc9b-dbe0ab8fec0f' User entered '22 Aug 2020 07:09'	System	22 Aug 2020 11:09:08
	System	22 Aug 2020 11:09:08

**US3762023**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Aug 2020 19:50'	System	21 Aug 2020 20:18:34



**US3762023**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 2'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:44', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545' User entered 'None (0)'	System	22 Aug 2020 16:02:11
	System	22 Aug 2020 16:02:11

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545' User entered 'None (0)'	System	22 Aug 2020 16:02:11
	System	22 Aug 2020 16:02:11

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:52', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545' User entered 'None (0)'	System	22 Aug 2020 16:02:11
	System	22 Aug 2020 16:02:11

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545' User entered 'None (0)'	System	22 Aug 2020 16:02:11
	System	22 Aug 2020 16:02:11

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:01:58', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545' User entered 'None (0)'	System	22 Aug 2020 16:02:11
	System	22 Aug 2020 16:02:11

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:02:01', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545'	System	22 Aug 2020 16:02:11
User entered 'None (0)'	System	22 Aug 2020 16:02:11



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:02:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545'	System	22 Aug 2020 16:02:11
User entered 'No (N)'	System	22 Aug 2020 16:02:11

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-22T12:02:09', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2afc25c2-f51f-40ca-a14b-3dc110c12545' User entered '22 Aug 2020 12:02'	System	22 Aug 2020 16:02:11
	System	22 Aug 2020 16:02:11

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 3'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:21', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'None (0)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'None (0)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'None (0)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:31', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'None (0)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:33', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'None (0)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'None (0)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2' User entered 'No (N)'	System	23 Aug 2020 21:17:52
	System	23 Aug 2020 21:17:52

**US3762023**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-23T17:17:50', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4895f198-9b02-496f-ac4e-961400a2acb2'	System	23 Aug 2020 21:17:52
User entered '23 Aug 2020 17:17'	System	23 Aug 2020 21:17:52

**US3762023**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 4'	System	21 Aug 2020 20:18:34



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:27', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'None (0)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'None (0)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'None (0)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'None (0)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:42', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'None (0)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:45', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'None (0)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:51', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered 'No (N)'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-24T12:40:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c02b59b-89ef-4b02-b8df-165860b43377' User entered '24 Aug 2020 12:40'	System	24 Aug 2020 16:40:59
	System	24 Aug 2020 16:40:59



**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 5'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:24', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'None (0)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:27', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'None (0)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'None (0)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'None (0)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'None (0)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53



**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'None (0)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:44', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered 'No (N)'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-26T07:40:52', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '27d55fb7-826d-4989-bc79-a8d8fa5b793b' User entered '26 Aug 2020 07:40'	System	26 Aug 2020 11:40:53
	System	26 Aug 2020 11:40:53

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 6'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'None (0)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:02', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'None (0)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:05', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'None (0)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:08', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'None (0)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:11', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'None (0)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:14', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'None (0)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:19', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered 'No (N)'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-27T08:12:23', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '0342e82d-6cc4-41e2-8f30-69c5ffb9ab6f' User entered '27 Aug 2020 08:12'	System	27 Aug 2020 12:12:27
	System	27 Aug 2020 12:12:27

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 20:18:34



US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 7'	System	21 Aug 2020 20:18:34

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:09', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'None (0)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:11', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'None (0)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:15', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'None (0)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:17', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'None (0)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:19', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'None (0)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'None (0)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

US3762023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered 'No (N)'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35



**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-08-28T10:14:33', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '03caa154-2661-44d1-9467-25c0f9e21753' User entered '28 Aug 2020 10:14'	System	28 Aug 2020 14:14:35
	System	28 Aug 2020 14:14:35

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 20:18:34

**US3762023**

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

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 20:18:34

**US3762023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	15 Sep 2020 15:03:57

**US3762023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '28 Aug 2020'	James Lovette (b) (4)	15 Sep 2020 15:03:57

**US3762023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4)	15 Sep 2020 15:03:57

**US3762023**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	James Lovette (b) (4)	15 Sep 2020 15:03:57

US3762023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	15 Sep 2020 15:04:09



**US3762023**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	15 Sep 2020 15:04:09

**US3762023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:32:58
User entered 'Yes (Y)'	James Lovette (b) (4)	15 Sep 2020 15:09:14

**US3762023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:32:58
User entered '04 Sep 2020'	(b) (4) James Lovette (b) (4)	15 Sep 2020 15:09:14

**US3762023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:32:58
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4)	15 Sep 2020 15:09:14

US3762023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:32:58
User entered empty.	James Lovette (b) (4)	15 Sep 2020 15:09:14

US3762023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:40:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:32:58
User entered 'Yes (Y)'	James Lovette (b) (4)	15 Sep 2020 15:09:22

**US3762023**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	15 Sep 2020 15:09:22

**US3762023**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:27



**US3762023**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:27

**US3762023**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:27

US3762023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:27

**US3762023**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:34

**US3762023**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	17 Sep 2020 18:32:34

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:49

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:49

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:49



**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'VISIT2'	System	17 Sep 2020 18:32:49

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Pre-Dose (PREDOSE)'	James Lovette (b) (4)	28 Sep 2020 14:30:14
	(b) (4)	

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	28 Sep 2020 14:30:14

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '17 Sep 2020'	James Lovette (b) (4)	28 Sep 2020 14:30:14

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '13:45'	James Lovette (b) (4)	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '17 Sep 2020 13:45'	System	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '97.9' F	James Lovette (b) (4)	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Oral (Oral)'	(b) (4) James Lovette (b) (4)	28 Sep 2020 14:30:14



**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	James Lovette (b) (4)	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '64'	James Lovette (b) (4)	28 Sep 2020 14:30:14

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'bpm'	System	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '10'	James Lovette (b) (4)	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'breaths/min'	System	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '134'	James Lovette (b) (4)	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '84'	James Lovette (b) (4)	28 Sep 2020 14:30:14



US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	28 Sep 2020 14:30:14

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Post-Dose (POSTDOSE)'	James Lovette (b) (4) (b) (4)	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	28 Sep 2020 14:31:31

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '17 Sep 2020'	James Lovette (b) (4)	28 Sep 2020 14:31:31

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '14:57'	James Lovette (b) (4)	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '17 Sep 2020 14:57'	System	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '97.5' F	James Lovette (b) (4)	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Oral (Oral)'	(b) (4) James Lovette (b) (4)	28 Sep 2020 14:31:31



**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	James Lovette (b) (4)	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '62'	James Lovette (b) (4)	28 Sep 2020 14:31:31

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'bpm'	System	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '24'	James Lovette (b) (4)	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'breaths/min'	System	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '137'	James Lovette (b) (4)	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '89'	James Lovette (b) (4)	28 Sep 2020 14:31:31



US3762023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	28 Sep 2020 14:31:31

US3762023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	28 Sep 2020 14:31:51

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '17 Sep 2020'	James Lovette (b) (4)	28 Sep 2020 14:31:51

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:45



US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '14:26'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:45

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '17 Sep 2020 14:26'	System	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'ONCE'	System	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 18:33:45

US3762023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	28 Sep 2020 14:32:22

US3762023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 07:01:32
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'all samples have been sent out' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	25 Oct 2020 19:52:58
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 11:14:06
User entered '17 Sep 2020'	James Lovette (b) (4) (b) (4)	28 Sep 2020 14:32:22

US3762023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '14:01'	James Lovette (b) (4)	28 Sep 2020 14:32:22



**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '17 Sep 2020 14:01'	System	28 Sep 2020 14:32:22

US3762023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:40:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '17 Sep 2020'	James Lovette (b) (4)	28 Sep 2020 14:32:46

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	James Lovette (b) (4) (b) (4)	28 Sep 2020 14:32:46

US3762023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	28 Sep 2020 14:32:46

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '13:55'	James Lovette (b) (4)	28 Sep 2020 14:32:46

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '17 Sep 2020 13:55'	System	28 Sep 2020 14:32:46

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	James Lovette (b) (4) (b) (4)	28 Sep 2020 14:32:46

US3762023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	James Lovette (b) (4)	28 Sep 2020 14:32:46



**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	James Lovette (b) (4)	28 Sep 2020 14:32:46

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered empty.	System	28 Sep 2020 14:32:46

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:55

**US3762023**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	17 Sep 2020 18:33:55

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:00:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '775a96c2-3180-4d43-be92-60e8e9033a73' User entered 'Yes (Y)'	System	17 Sep 2020 19:01:41
	System	17 Sep 2020 19:01:41

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:00:50', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '775a96c2-3180-4d43-be92-60e8e9033a73' User entered '97.5'	System	17 Sep 2020 19:01:41
	System	17 Sep 2020 19:01:41

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:00:55', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '775a96c2-3180-4d43-be92-60e8e9033a73'	System	17 Sep 2020 19:01:41
User entered 'No (N)'	System	17 Sep 2020 19:01:41



**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:01', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '775a96c2-3180-4d43-be92-60e8e9033a73' User entered '17 Sep 2020 15:01'	System	17 Sep 2020 19:01:41
	System	17 Sep 2020 19:01:41

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 14:46'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 17:16'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34



US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 18:11'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 2'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:26:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c9dc4906-71d3-42f7-83fe-903e0b94ac49' User entered 'Yes (Y)'	System	18 Sep 2020 21:27:01
	System	18 Sep 2020 21:27:01

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:26:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c9dc4906-71d3-42f7-83fe-903e0b94ac49' User entered '97.8'	System	18 Sep 2020 21:27:01
	System	18 Sep 2020 21:27:01

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:26:53', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c9dc4906-71d3-42f7-83fe-903e0b94ac49'	System	18 Sep 2020 21:27:01
User entered 'No (N)'	System	18 Sep 2020 21:27:01



**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:26:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c9dc4906-71d3-42f7-83fe-903e0b94ac49'	System	18 Sep 2020 21:27:01
User entered '18 Sep 2020 17:26'	System	18 Sep 2020 21:27:01

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 3'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-19T23:59:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '5e221017-7eea-43c5-9b2d-874d2d834e97' User entered 'Yes (Y)'	System	20 Sep 2020 03:59:52
	System	20 Sep 2020 03:59:52

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-19T23:59:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '5e221017-7eea-43c5-9b2d-874d2d834e97' User entered '98.0'	System	20 Sep 2020 03:59:52
	System	20 Sep 2020 03:59:52

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-19T23:59:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '5e221017-7eea-43c5-9b2d-874d2d834e97'	System	20 Sep 2020 03:59:52
User entered 'No (N)'	System	20 Sep 2020 03:59:52

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-19T23:59:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '5e221017-7eea-43c5-9b2d-874d2d834e97'	System	20 Sep 2020 03:59:52
User entered '19 Sep 2020 23:59'	System	20 Sep 2020 03:59:52



**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 4'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:18:23', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '723f7925-e4ce-48d6-9de6-9191df5e687f' User entered 'Yes (Y)'	System	21 Sep 2020 02:18:43
	System	21 Sep 2020 02:18:43

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:18:31', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '723f7925-e4ce-48d6-9de6-9191df5e687f' User entered '97.9'	System	21 Sep 2020 02:18:43
	System	21 Sep 2020 02:18:43

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:18:35', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '723f7925-e4ce-48d6-9de6-9191df5e687f' User entered 'No (N)'	System	21 Sep 2020 02:18:43
	System	21 Sep 2020 02:18:43

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:18:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '723f7925-e4ce-48d6-9de6-9191df5e687f' User entered '20 Sep 2020 22:18'	System	21 Sep 2020 02:18:43
	System	21 Sep 2020 02:18:43

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 5'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:45:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2deb8709-75f8-4db8-8845-3b2d17592f4f' User entered 'Yes (Y)'	System	22 Sep 2020 09:45:54
	System	22 Sep 2020 09:45:54

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:45:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2deb8709-75f8-4db8-8845-3b2d17592f4f' User entered '98.0'	System	22 Sep 2020 09:45:54
	System	22 Sep 2020 09:45:54

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:45:49', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2deb8709-75f8-4db8-8845-3b2d17592f4f' User entered 'No (N)'	System	22 Sep 2020 09:45:54
	System	22 Sep 2020 09:45:54

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:45:52', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '2deb8709-75f8-4db8-8845-3b2d17592f4f' User entered '22 Sep 2020 05:45'	System	22 Sep 2020 09:45:54
	System	22 Sep 2020 09:45:54

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 6'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:35:44', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c7d046ae-70c8-41ba-ba36-6f2a7b684960' User entered 'Yes (Y)'	System	23 Sep 2020 13:36:07
	System	23 Sep 2020 13:36:07

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:35:53', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c7d046ae-70c8-41ba-ba36-6f2a7b684960' User entered '98.7'	System	23 Sep 2020 13:36:07
	System	23 Sep 2020 13:36:07

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:35:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c7d046ae-70c8-41ba-ba36-6f2a7b684960'	System	23 Sep 2020 13:36:07
User entered 'No (N)'	System	23 Sep 2020 13:36:07

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:01', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c7d046ae-70c8-41ba-ba36-6f2a7b684960' User entered '23 Sep 2020 09:36'	System	23 Sep 2020 13:36:07
	System	23 Sep 2020 13:36:07

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 7'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:18', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'ca8a6043-93c7-4968-accd-91ca31a6e2b9' User entered 'Yes (Y)'	System	24 Sep 2020 13:22:44
	System	24 Sep 2020 13:22:44

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:27', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'ca8a6043-93c7-4968-accd-91ca31a6e2b9' User entered '97.9'	System	24 Sep 2020 13:22:44
	System	24 Sep 2020 13:22:44

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'ca8a6043-93c7-4968-accd-91ca31a6e2b9'	System	24 Sep 2020 13:22:44
User entered 'No (N)'	System	24 Sep 2020 13:22:44

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'ca8a6043-93c7-4968-accd-91ca31a6e2b9' User entered '24 Sep 2020 09:22'	System	24 Sep 2020 13:22:44
	System	24 Sep 2020 13:22:44

US3762023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:08', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '9ac5931a-811f-4e4d-849b-29ff4f7b742e' User entered 'None (1)'	System	17 Sep 2020 19:02:05
	System	17 Sep 2020 19:02:05



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:14', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '9ac5931a-811f-4e4d-849b-29ff4f7b742e' User entered 'No (N)'	System	17 Sep 2020 19:02:05
	System	17 Sep 2020 19:02:05

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:17', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '9ac5931a-811f-4e4d-849b-29ff4f7b742e' User entered 'No (N)'	System	17 Sep 2020 19:02:05
	System	17 Sep 2020 19:02:05

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '9ac5931a-811f-4e4d-849b-29ff4f7b742e' User entered 'None (1)'	System	17 Sep 2020 19:02:05
	System	17 Sep 2020 19:02:05

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '9ac5931a-811f-4e4d-849b-29ff4f7b742e' User entered '17 Sep 2020 15:01'	System	17 Sep 2020 19:02:05
	System	17 Sep 2020 19:02:05

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 14:46'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 17:16'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 18:11'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 2'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:10', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06f55bd1-4efe-4d72-a964-174985c4b62f' User entered 'None (1)'	System	18 Sep 2020 21:27:36
	System	18 Sep 2020 21:27:36

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:14', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06f55bd1-4efe-4d72-a964-174985c4b62f' User entered 'No (N)'	System	18 Sep 2020 21:27:36
	System	18 Sep 2020 21:27:36

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06f55bd1-4efe-4d72-a964-174985c4b62f' User entered 'No (N)'	System	18 Sep 2020 21:27:36
	System	18 Sep 2020 21:27:36

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:27', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06f55bd1-4efe-4d72-a964-174985c4b62f' User entered 'None (1)'	System	18 Sep 2020 21:27:36
	System	18 Sep 2020 21:27:36

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06f55bd1-4efe-4d72-a964-174985c4b62f' User entered '18 Sep 2020 17:27'	System	18 Sep 2020 21:27:36
	System	18 Sep 2020 21:27:36

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 3'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-19T23:59:54', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e721262f-585d-449a-9bce-94c15c96905d' User entered 'None (1)'	System	20 Sep 2020 04:00:15
	System	20 Sep 2020 04:00:15

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-19T23:59:57', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e721262f-585d-449a-9bce-94c15c96905d' User entered 'No (N)'	System	20 Sep 2020 04:00:15
	System	20 Sep 2020 04:00:15

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e721262f-585d-449a-9bce-94c15c96905d' User entered 'No (N)'	System	20 Sep 2020 04:00:15
	System	20 Sep 2020 04:00:15

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:04', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e721262f-585d-449a-9bce-94c15c96905d' User entered 'None (1)'	System	20 Sep 2020 04:00:15
	System	20 Sep 2020 04:00:15

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:07', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e721262f-585d-449a-9bce-94c15c96905d' User entered '20 Sep 2020 00:00'	System	20 Sep 2020 04:00:15
	System	20 Sep 2020 04:00:15

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 4'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:18:45', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a0acf754-cdb3-464c-9d10-e95304981ff0'	System	21 Sep 2020 02:19:28
User entered 'None (1)'	System	21 Sep 2020 02:19:28

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a0acf754-cdb3-464c-9d10-e95304981ff0'	System	21 Sep 2020 02:19:28
User entered 'No (N)'	System	21 Sep 2020 02:19:28

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:09', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a0acf754-cdb3-464c-9d10-e95304981ff0'	System	21 Sep 2020 02:19:28
User entered 'No (N)'	System	21 Sep 2020 02:19:28

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a0acf754-cdb3-464c-9d10-e95304981ff0'	System	21 Sep 2020 02:19:28
User entered 'None (1)'	System	21 Sep 2020 02:19:28

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a0acf754-cdb3-464c-9d10-e95304981ff0'	System	21 Sep 2020 02:19:28
User entered '20 Sep 2020 22:19'	System	21 Sep 2020 02:19:28

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 5'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:45:57', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '49fdbf79-be27-47ac-b96a-36985476a605'	System	22 Sep 2020 09:46:19
User entered 'None (1)'	System	22 Sep 2020 09:46:19

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '49fdbf79-be27-47ac-b96a-36985476a605'	System	22 Sep 2020 09:46:19
User entered 'No (N)'	System	22 Sep 2020 09:46:19

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '49fdbf79-be27-47ac-b96a-36985476a605'	System	22 Sep 2020 09:46:19
User entered 'No (N)'	System	22 Sep 2020 09:46:19

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:08', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '49fdbf79-be27-47ac-b96a-36985476a605' User entered 'None (1)'	System	22 Sep 2020 09:46:19
	System	22 Sep 2020 09:46:19

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:40:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:15', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '49fdbf79-be27-47ac-b96a-36985476a605' User entered '22 Sep 2020 05:46'	System	22 Sep 2020 09:46:19
	System	22 Sep 2020 09:46:19

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 6'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06d63460-875a-43b5-8405-01318ac9ca09' User entered 'None (1)'	System	23 Sep 2020 13:36:22
	System	23 Sep 2020 13:36:22

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:10', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06d63460-875a-43b5-8405-01318ac9ca09' User entered 'No (N)'	System	23 Sep 2020 13:36:22
	System	23 Sep 2020 13:36:22

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:13', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06d63460-875a-43b5-8405-01318ac9ca09' User entered 'No (N)'	System	23 Sep 2020 13:36:22
	System	23 Sep 2020 13:36:22

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:17', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06d63460-875a-43b5-8405-01318ac9ca09' User entered 'None (1)'	System	23 Sep 2020 13:36:22
	System	23 Sep 2020 13:36:22

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '06d63460-875a-43b5-8405-01318ac9ca09' User entered '23 Sep 2020 09:36'	System	23 Sep 2020 13:36:22
	System	23 Sep 2020 13:36:22

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:40:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 7'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '40e7d215-bc34-4208-9e59-ca16ac365837'	System	24 Sep 2020 13:22:53
User entered 'None (1)'	System	24 Sep 2020 13:22:53

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '40e7d215-bc34-4208-9e59-ca16ac365837' User entered 'No (N)'	System	24 Sep 2020 13:22:53
	System	24 Sep 2020 13:22:53

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:46', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '40e7d215-bc34-4208-9e59-ca16ac365837' User entered 'No (N)'	System	24 Sep 2020 13:22:53
	System	24 Sep 2020 13:22:53

US3762023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '40e7d215-bc34-4208-9e59-ca16ac365837' User entered 'None (1)'	System	24 Sep 2020 13:22:53
	System	24 Sep 2020 13:22:53

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:51', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '40e7d215-bc34-4208-9e59-ca16ac365837' User entered '24 Sep 2020 09:22'	System	24 Sep 2020 13:22:53
	System	24 Sep 2020 13:22:53

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'None (0)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:33', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'None (0)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:35', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'None (0)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:38', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'None (0)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'None (0)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'None (0)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered 'No (N)'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27



**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-17T15:01:50', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3c5f6291-27d1-4fe3-8492-308328f183f4' User entered '17 Sep 2020 15:01'	System	17 Sep 2020 19:02:27
	System	17 Sep 2020 19:02:27

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:40:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 14:46'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 17:16'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '17 Sep 2020 18:11'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 2'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'None (0)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:45', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'None (0)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:49', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'None (0)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:51', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'None (0)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:27:59', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'None (0)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:28:02', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'None (0)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:28:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered 'No (N)'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-18T17:28:08', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a9350b16-033a-4dfb-8753-d48ef0209c11' User entered '18 Sep 2020 17:28'	System	18 Sep 2020 21:28:10
	System	18 Sep 2020 21:28:10

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:33:45



**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 3'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:12', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'None (0)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:16', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'None (0)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:18', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'None (0)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:21', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'None (0)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:24', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'None (0)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'None (0)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered 'No (N)'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T00:00:35', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '50e07fa9-57ec-40e7-a22f-8e631b5a30ce' User entered '20 Sep 2020 00:00'	System	20 Sep 2020 04:00:41
	System	20 Sep 2020 04:00:41

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 4'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'None (0)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:31', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'None (0)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'None (0)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'None (0)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'None (0)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:41', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'None (0)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:44', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered 'No (N)'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-20T22:19:47', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b847fc18-a62e-4e72-a46a-69f0d187bee0' User entered '20 Sep 2020 22:19'	System	21 Sep 2020 02:19:50
	System	21 Sep 2020 02:19:50

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 5'	System	17 Sep 2020 18:33:45



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:19', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered 'None (0)'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:23', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered 'None (0)'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered 'None (0)'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered 'None (0)'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered 'None (0)'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered 'None (0)'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7'	System	22 Sep 2020 09:46:47
User entered 'No (N)'	System	22 Sep 2020 09:46:47

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-22T05:46:43', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '139ea949-4511-408a-aa4f-581555ba79f7' User entered '22 Sep 2020 05:46'	System	22 Sep 2020 09:46:47
	System	22 Sep 2020 09:46:47



**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 6'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:24', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'None (0)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'None (0)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'None (0)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'None (0)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'None (0)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42



**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:34', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'None (0)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered 'No (N)'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-23T09:36:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '6c0881c7-10f6-49aa-ba78-5f67780924c5' User entered '23 Sep 2020 09:36'	System	23 Sep 2020 13:36:42
	System	23 Sep 2020 13:36:42

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	17 Sep 2020 18:33:45
User entered 'Day 7'	System	17 Sep 2020 18:33:45

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:54', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'None (0)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:22:57', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'None (0)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16



US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:23:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'None (0)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:23:02', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'None (0)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:23:04', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'None (0)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:23:07', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'None (0)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

US3762023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:23:11', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered 'No (N)'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-09-24T09:23:14', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '8c78f09f-f9ce-4c72-922b-7c928333bc9d' User entered '24 Sep 2020 09:23'	System	24 Sep 2020 13:23:16
	System	24 Sep 2020 13:23:16

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:33:45

**US3762023**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:40:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:33:45



US3762023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 17:59:01
User entered 'Yes (Y)' reason for change: Data Entry Error	James Lovette (b) (4)	05 Oct 2020 17:59:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Oct 2020 17:55:20
	James Lovette (b) (4)	05 Oct 2020 17:55:20
	(b) (4)	

US3762023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	05 Oct 2020 18:00:43
User entered '24 Sep 2020' reason for change: Data Entry Error	James Lovette (b) (4)	05 Oct 2020 18:00:43
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '4 Sep 2020' reason for change: Data Entry Error	System	05 Oct 2020 17:59:01
User entered empty.	James Lovette (b) (4)	05 Oct 2020 17:59:01
	(b) (4)	
	James Lovette (b) (4)	05 Oct 2020 17:55:20
	(b) (4)	

US3762023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	James Lovette (b) (4)	05 Oct 2020 17:59:01
User entered empty.	(b) (4)	
	James Lovette (b) (4)	05 Oct 2020 17:55:20
	(b) (4)	

US3762023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'missed call' reason for change: Data Entry Error	(b) (4)	
	James Lovette (b) (4)	05 Oct 2020 17:59:01
User entered empty.	(b) (4)	
	James Lovette (b) (4)	05 Oct 2020 17:55:20
	(b) (4)	

**US3762023**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	05 Oct 2020 17:59:11

**US3762023**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	05 Oct 2020 17:59:11

**US3762023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	05 Oct 2020 18:01:59

**US3762023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '02 Oct 2020'	James Lovette (b) (4)	05 Oct 2020 18:01:59



**US3762023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4)	05 Oct 2020 18:01:59

US3762023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	James Lovette (b) (4)	05 Oct 2020 18:01:59

**US3762023**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	James Lovette (b) (4)	05 Oct 2020 18:02:10

**US3762023**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	05 Oct 2020 18:02:10

**US3762023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:51:56

**US3762023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:51:56

**US3762023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:51:56

**US3762023**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:51:56



**US3762023**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:01

**US3762023**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	19 Oct 2020 21:52:01

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:12

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:12

US3762023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:40:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:12

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'VISIT3'	System	19 Oct 2020 21:52:12

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52



**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '13:35'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '16 Oct 2020 13:35'	System	19 Oct 2020 21:52:52

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '67'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'bpm'	System	19 Oct 2020 21:52:52

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52



US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'breaths/min'	System	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '139'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	19 Oct 2020 21:52:52

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '93'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:52

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'mmHg'	System	19 Oct 2020 21:52:52

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15

US3762023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:17



US3762023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:52:17

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:53:06

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:53:06

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered '13:56'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:53:06

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered '16 Oct 2020 13:56'	System	19 Oct 2020 21:53:06

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 22:33:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:53:10

**US3762023**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	19 Oct 2020 21:53:10

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 64'	System	21 Aug 2020 20:18:34



US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

[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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-10-23T12:00:33', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '60847d02-a9d8-4110-9bc2-1a65655a01e3'	System	23 Oct 2020 16:01:35
User entered 'No (N)'	System	23 Oct 2020 16:01:35

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-10-23T12:00:40', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '60847d02-a9d8-4110-9bc2-1a65655a01e3'	System	23 Oct 2020 16:01:35
User entered 'No (N)'	System	23 Oct 2020 16:01:35

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-10-23T12:00:59', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '60847d02-a9d8-4110-9bc2-1a65655a01e3' User entered '23 Oct 2020 12:00:59'	System	23 Oct 2020 16:01:35
	System	23 Oct 2020 16:01:35

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 71'	System	21 Aug 2020 20:18:34

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

[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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-10-31T17:20:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '486964c7-cbb2-4de0-b285-6f956f914d7d' User entered 'No (N)'	System	31 Oct 2020 21:20:30
	System	31 Oct 2020 21:20:30

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-10-31T17:20:24', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '486964c7-cbb2-4de0-b285-6f956f914d7d' User entered 'No (N)'	System	31 Oct 2020 21:20:30
	System	31 Oct 2020 21:20:30



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-10-31T17:20:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '486964c7-cbb2-4de0-b285-6f956f914d7d' User entered '31 Oct 2020 17:20:28'	System	31 Oct 2020 21:20:30
	System	31 Oct 2020 21:20:30

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 78'	System	21 Aug 2020 20:18:34

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

[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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-07T06:28:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c331bbd7-950b-4909-9604-73a6eb026160' User entered 'No (N)'	System	07 Nov 2020 11:28:34
	System	07 Nov 2020 11:28:34

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-07T06:28:24', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c331bbd7-950b-4909-9604-73a6eb026160' User entered 'No (N)'	System	07 Nov 2020 11:28:34
	System	07 Nov 2020 11:28:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-07T06:28:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'c331bbd7-950b-4909-9604-73a6eb026160' User entered '07 Nov 2020 06:28:29'	System	07 Nov 2020 11:28:34
	System	07 Nov 2020 11:28:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 20:18:34



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered 'Day 92'	System	21 Aug 2020 20:18:34

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-18T07:16:18', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '24cbf068-06a2-4a6a-aef6-6a84f6ba00ba' User entered 'No (N)'	System	18 Nov 2020 12:16:30
	System	18 Nov 2020 12:16:30

US3762023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:40:55

Have you been exposed to someone with 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)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-18T07:16:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '24cbf068-06a2-4a6a-aef6-6a84f6ba00ba' User entered 'No (N)'	System	18 Nov 2020 12:16:30
	System	18 Nov 2020 12:16:30

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-18T07:16:28', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '24cbf068-06a2-4a6a-aef6-6a84f6ba00ba' User entered '18 Nov 2020 07:16:28'	System	18 Nov 2020 12:16:30
	System	18 Nov 2020 12:16:30

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:23:34
Data entry locked.	System	21 Aug 2020 20:18:34
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 20:18:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:55:45



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-22T08:03:24', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '156af213-3364-4bda-a061-82b1a9038a5d' User entered 'No (N)'	System	22 Nov 2020 13:04:06
	System	22 Nov 2020 13:04:06

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-22T08:03:41', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '156af213-3364-4bda-a061-82b1a9038a5d' User entered 'No (N)'	System	22 Nov 2020 13:04:06
	System	22 Nov 2020 13:04:06

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-11-22T08:04:02', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '156af213-3364-4bda-a061-82b1a9038a5d' User entered '22 Nov 2020 08:04:02'	System	22 Nov 2020 13:04:06
	System	22 Nov 2020 13:04:06

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-02T17:59:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd4fc562e-9510-4ebd-9681-a7421f8149fa' User entered 'No (N)'	System	02 Dec 2020 22:59:51
	System	02 Dec 2020 22:59:51

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-02T17:59:41', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd4fc562e-9510-4ebd-9681-a7421f8149fa' User entered 'No (N)'	System	02 Dec 2020 22:59:51
	System	02 Dec 2020 22:59:51



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-02T17:59:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd4fc562e-9510-4ebd-9681-a7421f8149fa' User entered '02 Dec 2020 17:59:48'	System	02 Dec 2020 22:59:51
	System	02 Dec 2020 22:59:51

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-08T12:00:52', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '495a64cb-1e7b-475d-bee8-8fbaaaf13084' User entered 'No (N)'	System	08 Dec 2020 17:01:19
	System	08 Dec 2020 17:01:19

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-08T12:00:58', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '495a64cb-1e7b-475d-bee8-8fbaaaf13084' User entered 'No (N)'	System	08 Dec 2020 17:01:19
	System	08 Dec 2020 17:01:19

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-08T12:01:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '495a64cb-1e7b-475d-bee8-8fbaaaf13084' User entered '08 Dec 2020 12:01:03'	System	08 Dec 2020 17:01:19
	System	08 Dec 2020 17:01:19

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-13T06:20:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b4455a97-c33c-4e8a-a994-5aaedd7cf7ef' User entered 'No (N)'	System	13 Dec 2020 11:20:50
	System	13 Dec 2020 11:20:50

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-13T06:20:41', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b4455a97-c33c-4e8a-a994-5aaedd7cf7ef' User entered 'No (N)'	System	13 Dec 2020 11:20:50
	System	13 Dec 2020 11:20:50

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-13T06:20:48', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'b4455a97-c33c-4e8a-a994-5aaedd7cf7ef' User entered '13 Dec 2020 06:20:48'	System	13 Dec 2020 11:20:50
	System	13 Dec 2020 11:20:50

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:55:45



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-20T00:01:49', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '362646e9-0705-4068-bfa4-f72990dc3e11' User entered 'No (N)'	System	20 Dec 2020 05:02:26
	System	20 Dec 2020 05:02:26

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-20T00:01:56', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '362646e9-0705-4068-bfa4-f72990dc3e11' User entered 'No (N)'	System	20 Dec 2020 05:02:26
	System	20 Dec 2020 05:02:26

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-20T00:02:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '362646e9-0705-4068-bfa4-f72990dc3e11' User entered '20 Dec 2020 00:02:03'	System	20 Dec 2020 05:02:26
	System	20 Dec 2020 05:02:26

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-29T12:00:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '837e8d8e-f50c-486b-a17a-61576efbd2e6' User entered 'No (N)'	System	29 Dec 2020 17:00:40
	System	29 Dec 2020 17:00:40

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-29T12:00:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '837e8d8e-f50c-486b-a17a-61576efbd2e6' User entered 'No (N)'	System	29 Dec 2020 17:00:40
	System	29 Dec 2020 17:00:40



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2020-12-29T12:00:36', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '837e8d8e-f50c-486b-a17a-61576efbd2e6' User entered '29 Dec 2020 12:00:36'	System	29 Dec 2020 17:00:40
	System	29 Dec 2020 17:00:40

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-03T00:51:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a71a05a9-583d-46ae-ad6d-946e360adfb8' User entered 'No (N)'	System	03 Jan 2021 05:51:34
	System	03 Jan 2021 05:51:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-03T00:51:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a71a05a9-583d-46ae-ad6d-946e360adfb8'	System	03 Jan 2021 05:51:34
User entered 'No (N)'	System	03 Jan 2021 05:51:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-03T00:51:31', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'a71a05a9-583d-46ae-ad6d-946e360adfb8' User entered '03 Jan 2021 00:51:31'	System	03 Jan 2021 05:51:34
	System	03 Jan 2021 05:51:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-10T07:42:42', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'adc5faae-699c-4e87-8111-a580a3a76571' User entered 'No (N)'	System	11 Jan 2021 11:15:45
	System	11 Jan 2021 11:15:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-10T07:42:47', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'adc5faae-699c-4e87-8111-a580a3a76571'	System	11 Jan 2021 11:15:45
User entered 'No (N)'	System	11 Jan 2021 11:15:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-10T07:42:51', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'adc5faae-699c-4e87-8111-a580a3a76571' User entered '10 Jan 2021 07:42:51'	System	11 Jan 2021 11:15:45
	System	11 Jan 2021 11:15:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:55:45



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-17T16:53:27', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1a2b7ab1-fcac-4088-b0e5-6b3237c85224'	System	17 Jan 2021 21:53:40
User entered 'No (N)'	System	17 Jan 2021 21:53:40

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-17T16:53:32', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1a2b7ab1-fcac-4088-b0e5-6b3237c85224'	System	17 Jan 2021 21:53:40
User entered 'No (N)'	System	17 Jan 2021 21:53:40

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-17T16:53:37', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1a2b7ab1-fcac-4088-b0e5-6b3237c85224' User entered '17 Jan 2021 16:53:37'	System	17 Jan 2021 21:53:40
	System	17 Jan 2021 21:53:40

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-24T15:33:22', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3dfb034f-2fe7-44b8-8ebc-87ec8f713495'	System	24 Jan 2021 20:33:31
User entered 'No (N)'	System	24 Jan 2021 20:33:31

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-24T15:33:26', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3dfb034f-2fe7-44b8-8ebc-87ec8f713495'	System	24 Jan 2021 20:33:31
User entered 'No (N)'	System	24 Jan 2021 20:33:31



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-24T15:33:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '3dfb034f-2fe7-44b8-8ebc-87ec8f713495' User entered '24 Jan 2021 15:33:29'	System	24 Jan 2021 20:33:31
	System	24 Jan 2021 20:33:31

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-31T06:42:15', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '16217bd2-4652-4e28-b494-d948c1ded0d3'	System	31 Jan 2021 11:42:56
User entered 'Yes (Y)'	System	31 Jan 2021 11:42:56

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-31T06:42:20', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '16217bd2-4652-4e28-b494-d948c1ded0d3'	System	31 Jan 2021 11:42:56
User entered 'No (N)'	System	31 Jan 2021 11:42:56

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-31T06:42:23', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '16217bd2-4652-4e28-b494-d948c1ded0d3'	System	31 Jan 2021 11:42:56
User entered 'No (N)'	System	31 Jan 2021 11:42:56

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-31T06:42:29', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '16217bd2-4652-4e28-b494-d948c1ded0d3'	System	31 Jan 2021 11:42:56
User entered 'Yes (Y)'	System	31 Jan 2021 11:42:56



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-31T06:42:39', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '16217bd2-4652-4e28-b494-d948c1ded0d3'	System	31 Jan 2021 11:42:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 11:42:56

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-01-31T06:42:47', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '16217bd2-4652-4e28-b494-d948c1ded0d3' User entered '31 Jan 2021 06:42:47'	System	31 Jan 2021 11:42:56
	System	31 Jan 2021 11:42:56

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-08T06:54:21', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '71eb54d6-c2f9-4f62-bdcd-56fd8a180811' User entered 'No (N)'	System	08 Feb 2021 11:54:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-08T06:54:25', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '71eb54d6-c2f9-4f62-bdcd-56fd8a180811'	System	08 Feb 2021 11:54:34
User entered 'No (N)'	System	08 Feb 2021 11:54:34

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-08T06:54:30', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '71eb54d6-c2f9-4f62-bdcd-56fd8a180811' User entered '08 Feb 2021 06:54:30'	System	08 Feb 2021 11:54:34
	System	08 Feb 2021 11:54:34



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-14T07:41:05', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2ef2cc4-3b69-428d-9d22-69389251fd00'	System	14 Feb 2021 12:41:15
User entered 'No (N)'	System	14 Feb 2021 12:41:15

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-14T07:41:09', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2ef2cc4-3b69-428d-9d22-69389251fd00'	System	14 Feb 2021 12:41:15
User entered 'No (N)'	System	14 Feb 2021 12:41:15

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-14T07:41:13', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'd2ef2cc4-3b69-428d-9d22-69389251fd00' User entered '14 Feb 2021 07:41:13'	System	14 Feb 2021 12:41:15
	System	14 Feb 2021 12:41:15

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-21T07:42:59', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e4e068f1-2565-4ba4-aa92-3259f6e5bb20'	System	21 Feb 2021 12:43:08
User entered 'No (N)'	System	21 Feb 2021 12:43:08

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-21T07:43:03', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e4e068f1-2565-4ba4-aa92-3259f6e5bb20'	System	21 Feb 2021 12:43:08
User entered 'No (N)'	System	21 Feb 2021 12:43:08

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-21T07:43:06', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'e4e068f1-2565-4ba4-aa92-3259f6e5bb20' User entered '21 Feb 2021 07:43:06'	System	21 Feb 2021 12:43:08
	System	21 Feb 2021 12:43:08

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-28T11:33:34-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4748e9a2-a302-4d8d-bec2-c1ff58d3160d' User entered 'No (N)'	System	28 Feb 2021 16:33:44
	System	28 Feb 2021 16:33:44



**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-28T11:33:37-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4748e9a2-a302-4d8d-bec2-c1ff58d3160d' User entered 'No (N)'	System	28 Feb 2021 16:33:44

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-28T11:33:40-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4748e9a2-a302-4d8d-bec2-c1ff58d3160d' User entered '28 Feb 2021 16:33:40'	System	28 Feb 2021 16:33:44
	System	28 Feb 2021 16:33:44

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-07T08:09:19-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1424f4dd-ad3f-4858-95a8-ddf33f39a893'	System	07 Mar 2021 13:09:30
User entered 'No (N)'	System	07 Mar 2021 13:09:30

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-07T08:09:23-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1424f4dd-ad3f-4858-95a8-ddf33f39a893'	System	07 Mar 2021 13:09:30
User entered 'No (N)'	System	07 Mar 2021 13:09:30

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-07T08:09:27-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1424f4dd-ad3f-4858-95a8-ddf33f39a893'	System	07 Mar 2021 13:09:30
User entered '07 Mar 2021 08:09:27'	System	07 Mar 2021 13:09:30



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-15T17:05:35-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cf7179b8-d7b6-46f1-837f-bffaa3093d12'	System	15 Mar 2021 21:05:46
User entered 'No (N)'	System	15 Mar 2021 21:05:46

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-15T17:05:39-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cf7179b8-d7b6-46f1-837f-bffaa3093d12'	System	15 Mar 2021 21:05:46
User entered 'No (N)'	System	15 Mar 2021 21:05:46

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-15T17:05:42-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cf7179b8-d7b6-46f1-837f-bffaa3093d12' User entered '15 Mar 2021 17:05:42'	System	15 Mar 2021 21:05:46
	System	15 Mar 2021 21:05:46

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-24T17:59:19-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '58e56641-f4e6-4dc5-8754-0e65533a3950'	System	24 Mar 2021 21:59:29
User entered 'No (N)'	System	24 Mar 2021 21:59:29

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-24T17:59:23-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '58e56641-f4e6-4dc5-8754-0e65533a3950'	System	24 Mar 2021 21:59:29
User entered 'No (N)'	System	24 Mar 2021 21:59:29

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-24T17:59:26-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '58e56641-f4e6-4dc5-8754-0e65533a3950' User entered '24 Mar 2021 17:59:26'	System	24 Mar 2021 21:59:29
	System	24 Mar 2021 21:59:29

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-30T14:33:46-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fa24ebb6-aa22-4067-bd13-46d0107d0ad2'	System	30 Mar 2021 18:34:02
User entered 'No (N)'	System	30 Mar 2021 18:34:02



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-30T14:33:53-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fa24ebb6-aa22-4067-bd13-46d0107d0ad2'	System	30 Mar 2021 18:34:02
User entered 'No (N)'	System	30 Mar 2021 18:34:02

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-03-30T14:33:57-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'fa24ebb6-aa22-4067-bd13-46d0107d0ad2' User entered '30 Mar 2021 14:33:57'	System	30 Mar 2021 18:34:02
	System	30 Mar 2021 18:34:02

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-04T06:22:14-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '451a06a7-8512-4ab4-9d2b-a54f9131dc38'	System	04 Apr 2021 10:22:24
User entered 'No (N)'	System	04 Apr 2021 10:22:24

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-04T06:22:17-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '451a06a7-8512-4ab4-9d2b-a54f9131dc38'	System	04 Apr 2021 10:22:24
User entered 'No (N)'	System	04 Apr 2021 10:22:24

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-04T06:22:22-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '451a06a7-8512-4ab4-9d2b-a54f9131dc38'	System	04 Apr 2021 10:22:24
User entered '04 Apr 2021 06:22:22'	System	04 Apr 2021 10:22:24



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-11T07:14:31-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1439c666-c249-4bb2-8103-142eb21ca486'	System	11 Apr 2021 11:14:40
User entered 'No (N)'	System	11 Apr 2021 11:14:40

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-11T07:14:33-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1439c666-c249-4bb2-8103-142eb21ca486'	System	11 Apr 2021 11:14:40
User entered 'No (N)'	System	11 Apr 2021 11:14:40

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-11T07:14:38-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '1439c666-c249-4bb2-8103-142eb21ca486'	System	11 Apr 2021 11:14:40
User entered '11 Apr 2021 07:14:38'	System	11 Apr 2021 11:14:40

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-18T09:02:56-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f8f11b99-0195-419d-979e-be92e2066d76'	System	18 Apr 2021 13:03:38
User entered 'No (N)'	System	18 Apr 2021 13:03:38

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-18T09:03:17-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f8f11b99-0195-419d-979e-be92e2066d76'	System	18 Apr 2021 13:03:38
User entered 'No (N)'	System	18 Apr 2021 13:03:38

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-18T09:03:35-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'f8f11b99-0195-419d-979e-be92e2066d76'	System	18 Apr 2021 13:03:38
User entered '18 Apr 2021 09:03:35'	System	18 Apr 2021 13:03:38

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-25T12:12:53-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4efdbc41-9ac8-4446-af64-55f57c3554be'	System	25 Apr 2021 16:13:03
User entered 'No (N)'	System	25 Apr 2021 16:13:03



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-25T12:12:56-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4efdbc41-9ac8-4446-af64-55f57c3554be'	System	25 Apr 2021 16:13:03
User entered 'No (N)'	System	25 Apr 2021 16:13:03

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-04-25T12:12:59-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4efdbc41-9ac8-4446-af64-55f57c3554be' User entered '25 Apr 2021 12:12:59'	System	25 Apr 2021 16:13:03
	System	25 Apr 2021 16:13:03

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-05-02T05:06:04-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4bb75427-5d32-4359-8c11-2e8c8f878b78'	System	02 May 2021 09:06:14
User entered 'No (N)'	System	02 May 2021 09:06:14

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

Have you been exposed to someone with 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 (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-05-02T05:06:07-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4bb75427-5d32-4359-8c11-2e8c8f878b78'	System	02 May 2021 09:06:14
User entered 'No (N)'	System	02 May 2021 09:06:14

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-05-02T05:06:10-04:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: '4bb75427-5d32-4359-8c11-2e8c8f878b78'	System	02 May 2021 09:06:14
User entered '02 May 2021 05:06:10'	System	02 May 2021 09:06:14



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:55:45

**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:55:45



**US3762023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:40:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:55:45
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:55:45

US3762023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:40:55

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)	29 Apr 2021 19:19:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-27T13:56:59-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cc4f8098-f0b5-45a5-a599-6fe54cb594e3'	System	27 Feb 2021 18:57:06
User entered 'No (N)'	System	27 Feb 2021 18:57:06

**US3762023**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:19:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E8BE858-C881-41DC-AD63-90457230B4DB)', Time: '2021-02-27T13:57:04-05:00', User OID: 'PatientReportedOutcome (US3762023)', ODM File OID: 'cc4f8098-f0b5-45a5-a599-6fe54cb594e3' User entered '27 Feb 2021 18:57:04'	System	27 Feb 2021 18:57:06
	System	27 Feb 2021 18:57:06

**US3762023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:25:09
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	10 Nov 2020 14:35:22

**US3762023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:25:09
User entered '09 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	10 Nov 2020 14:35:22

**US3762023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:25:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	10 Nov 2020 14:35:22

**US3762023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:25:09
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	10 Nov 2020 14:35:22

**US3762023**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:25:09
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	10 Nov 2020 14:35:27



**US3762023**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:14:15
User entered 'I'	System	10 Nov 2020 14:35:27

**US3762023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Dec 2020 19:27:23

**US3762023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '14 Dec 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Dec 2020 19:27:23

**US3762023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Dec 2020 19:27:23

**US3762023**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Dec 2020 19:27:23

**US3762023**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Dec 2020 19:27:28

**US3762023**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User entered 'I'	System	14 Dec 2020 19:27:28

**US3762023**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:57:53



US3762023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:22:16
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'date is correct per source' (Site from System).	Samantha Wheeler (b) (4) (b) (4)	19 Jan 2021 22:36:52
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	19 Jan 2021 13:57:53
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 13:57:53

**US3762023**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:57:53

**US3762023**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:57:53

**US3762023**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:57:58

**US3762023**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User entered '1'	System	19 Jan 2021 13:57:58

**US3762023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:59:27

**US3762023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:59:27

**US3762023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:59:27



**US3762023**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:59:27

**US3762023**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:59:39

**US3762023**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:18:09
User entered 'I'	System	12 Feb 2021 16:59:39

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:12:37

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:12:37

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:12:37

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered 'VISIT4'	System	15 Mar 2021 19:12:37

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 14:37:03
User entered 'No (N)'	Kaitlyn Van Leuvan	30 Mar 2021 18:37:17
	(b) (4)	



US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08 Mar 2021' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan	30 Mar 2021 18:37:17
	(b) (4)	

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Apr 2021 14:37:56
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Apr 2021 14:37:56
User entered '08:32' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	08 Apr 2021 14:37:56
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan (b) (4)	30 Mar 2021 18:37:17

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered '08 Mar 2021 08:32'	System	08 Apr 2021 14:37:56
User entered empty.	System	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Apr 2021 14:37:56
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Apr 2021 14:37:56
User entered '97.7' F reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	08 Apr 2021 14:37:56
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan (b) (4)	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 14:37:56
User entered empty.	Kaitlyn Van Leuvan	30 Mar 2021 18:37:17
	(b) (4)	

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '74' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan	30 Mar 2021 18:37:17
	(b) (4)	

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered 'bpm'	System	08 Apr 2021 14:37:03
User entered empty.	System	30 Mar 2021 18:37:17



US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '16' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan	30 Mar 2021 18:37:17
	(b) (4)	

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered 'breaths/min'	System	08 Apr 2021 14:37:03
User entered empty.	System	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Apr 2021 14:37:32
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Apr 2021 14:37:32
User entered '148' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	08 Apr 2021 14:37:32
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan (b) (4)	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered 'mmHg'	System	08 Apr 2021 14:37:32
User entered empty.	System	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Apr 2021 14:38:15
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Apr 2021 14:38:15
User entered '76' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	08 Apr 2021 14:38:15
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 14:37:03
User entered empty.	Kaitlyn Van Leuvan (b) (4)	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered 'mmHg'	System	08 Apr 2021 14:38:15
User entered empty.	System	30 Mar 2021 18:37:17

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44

US3762023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44



**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:12:43

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:12:43

US3762023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:40:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:13:03

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:13:03

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '8:39'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:13:03

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered '8 Mar 2021 8:39'	System	15 Mar 2021 19:13:03

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:13:09

**US3762023**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:03:44
User entered 'I'	System	15 Mar 2021 19:13:09



**US3762023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:32:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:09:57

**US3762023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:32:21
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:09:57

**US3762023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:32:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:09:57

**US3762023**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:32:21
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:09:57

**US3762023**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:32:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:10:07

**US3762023**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 16:10:07

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:20

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:20



**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[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 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:20

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 13:59:20

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:37

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:18:20

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:37

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:18:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:40:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:37

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:40:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:37



**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 12:35:38
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 13:59:37

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 12:35:38
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 13:59:37

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:37

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:40:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '1'	System	11 Jan 2021 13:59:37

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'I'	System	11 Jan 2021 13:59:37

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '74' in	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '246' lb	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:40:55**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '31.65057'	System	11 Jan 2021 14:55:34
DataPoint set to visible.	System	11 Jan 2021 13:59:37



US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '74' in	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '246' lb	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:40:55**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '31.65057'	System	11 Jan 2021 14:55:34
DataPoint set to visible.	System	11 Jan 2021 13:59:37

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User accepted default value 'Pre-Dose (PREDOSE)'	Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:11'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '11 Jan 2021 08:11'	System	11 Jan 2021 14:55:34



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '97.6' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '64'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'bpm'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '15'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'breaths/min'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '151'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34



**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mmHg'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '93'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mmHg'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '74' in	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:40:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '246' lb	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:40:55**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '31.65057'	System	11 Jan 2021 14:55:34
DataPoint set to visible.	System	11 Jan 2021 13:59:37

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User accepted default value 'Post-Dose (POSTDOSE)'	Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34



US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '09:27'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '11 Jan 2021 09:27'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '97.5' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '58'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'bpm'	System	11 Jan 2021 14:55:34



US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '15'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'breaths/min'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '141'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mmHg'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '82'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:34

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mmHg'	System	11 Jan 2021 14:55:34

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:43

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:40:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:43



US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:54

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:54

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:54

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'mRNA-1273'	System	11 Jan 2021 13:59:54
DataPoint set to visible.	System	11 Jan 2021 13:59:37

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:54

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:57'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:54

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '11 Jan 2021 08:57'	System	11 Jan 2021 13:59:54

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 13:59:54



US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'ONCE'	System	11 Jan 2021 13:59:54

US3762023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 13:59:54

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:58

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:58

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:15'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:55:58

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered '11 Jan 2021 08:15'	System	11 Jan 2021 14:55:58

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:56:14

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '11 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:56:14



**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:17'	(b) (4) Kaitlyn Van Leuvan (b) (4)	11 Jan 2021 14:56:14

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:40:55**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered '11 Jan 2021 08:17'	System	11 Jan 2021 14:56:14

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 14:00:00

**US3762023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:43
User entered 'I'	System	11 Jan 2021 14:00:00

**US3762023**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Jan 2021 15:53:42

US3762023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:40:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 08:25:57
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct per source' (Site from System).	Kaitlyn Van Leuvan (b) (4)	17 Feb 2021 15:24:48
Amendment Manager: User opened query 'OL Safety System Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		17 Feb 2021 01:20:26
User entered '14 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	14 Jan 2021 15:53:42

**US3762023**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Jan 2021 15:53:42

**US3762023**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Jan 2021 15:53:42



**US3762023**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	14 Jan 2021 15:53:50

**US3762023**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User entered 'I'	System	14 Jan 2021 15:53:50

**US3762023**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:30:31
User entered '1'	System	14 Jan 2021 15:53:50
DataPoint set to visible.	System	14 Jan 2021 15:53:50

**US3762023**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:36:44

**US3762023**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:36:44

**US3762023**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[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 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:36:44

**US3762023**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'OLD29'	System	08 Feb 2021 14:36:44

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 14:37:54



**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:17'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered '8 Feb 2021 08:17'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '79'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54



**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'bpm'	System	08 Feb 2021 14:37:54

US3762023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '15'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'breaths/min'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '150'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'mmHg'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '86'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'mmHg'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 14:37:54



**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '09:29'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered '8 Feb 2021 09:29'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '76'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54



**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'bpm'	System	08 Feb 2021 14:37:54

US3762023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

US3762023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'breaths/min'	System	08 Feb 2021 14:37:54

US3762023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:40:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '155'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'mmHg'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '88'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'mmHg'	System	08 Feb 2021 14:37:54

**US3762023**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:02



**US3762023**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:02

**US3762023**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:24

**US3762023**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:24

US3762023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

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 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:24

**US3762023**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'mRNA-1273'	System	08 Feb 2021 14:38:24
DataPoint set to visible.	System	14 Jan 2021 15:53:50

US3762023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:24

**US3762023**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered '08:57'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:24

**US3762023**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:40:55**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered '8 Feb 2021 08:57'	System	08 Feb 2021 14:38:24



US3762023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:24

US3762023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'ONCE'	System	08 Feb 2021 14:38:24

US3762023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:40:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 14:38:24

**US3762023**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:38:31

**US3762023**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:28:29
User entered 'I'	System	08 Feb 2021 14:38:31

**US3762023**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:37:21

**US3762023**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:37:21

**US3762023**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:37:21



**US3762023**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:40:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:37:21

**US3762023**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:37:27

**US3762023**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:40:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:42:24
User entered 'I'	System	15 Feb 2021 15:37:27

**US3762023**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:04

**US3762023**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08 Mar 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:04

**US3762023**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[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 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Clinic (Clinic)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:04

**US3762023**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:40:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered 'OLD57'	System	08 Mar 2021 13:40:04

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45



**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08 Mar 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:32'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered '08 Mar 2021 08:32'	System	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '97.7' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '74'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered 'bpm'	System	08 Mar 2021 13:40:45



US3762023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:40:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '16'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered 'breaths/min'	System	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '148'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered 'mmHg'	System	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '76'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered 'mmHg'	System	08 Mar 2021 13:40:45

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17

**US3762023**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:40:55**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17



**US3762023**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:53

**US3762023**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:40:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:40:53

**US3762023**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:43:32

**US3762023**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08 Mar 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:43:32

**US3762023**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
User entered '08:39'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:43:32

**US3762023**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:40:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:33:17
User entered '08 Mar 2021 08:39'	System	08 Mar 2021 13:43:32

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:40:55**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:36:43
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:40
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:37:08

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:15:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:45:53
User entered		
'USA-US130-2021-mRNA-1273-P301000004'	System	02 Feb 2021 15:45:49
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 15:45:49



US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac valve disorders, HLT: Aortic valvular disorders, PT: Aortic valve incompetence, LLT: Aortic valve insufficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 11:24:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 11:24:24
Data point term sent to Coder	System	01 Feb 2021 19:57:11
Coding entries removed.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 19:56:42
User entered 'AORTIC VALVE Failure' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 19:56:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Aortic valve replacement, LLT: Aortic valve replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 17:47:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 17:47:30
Data point term sent to Coder	System	01 Feb 2021 17:46:08
User entered 'Aortic Valve Replacement'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '26 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Feb 2021 21:35:59
User entered empty; reason for change Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:35:59
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	01 Feb 2021 17:45:20
User entered '19:06'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 21:35:59
User entered '26 Jan 2021 19:06'	System	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20



**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '30 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

US3762023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	01 Feb 2021 21:35:59
User entered empty; reason for change Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:35:59
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	01 Feb 2021 17:45:20
User entered '17:03'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 21:35:59
User entered '30 Jan 2021 17:03'	System	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:36:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 21:36:39
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:36:39
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:20
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'I'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20



**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '26 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '30 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:36:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 21:36:39
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:36:39
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:20
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:36:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 21:36:39
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:36:39
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:20
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

**US3762023**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:36:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 21:36:39
User entered 'None (NONE)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:36:39
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 17:45:20
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:15:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure. However, there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:11:44
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure. However, there is no Concomitant Medication/Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication/Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:07:41
User entered 'I'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'Per CDM: Concomitant Procedure is checked however corresponding Concomitant Procedure page is blank. Please review and update accordingly.	(b) (4), (b) (6)	12 Feb 2021 13:41:42
' (Site from DM).		
Query 'Per CDM: Concomitant Procedure is checked however corresponding Concomitant Procedure page is blank. Please review and update accordingly.	Samantha Wheeler (b) (4)	11 Feb 2021 16:06:50
	(b) (4)	
' answered with 'procedure added' (Site from DM).		
User opened query 'Per CDM: Concomitant Procedure is checked however corresponding Concomitant Procedure page is blank. Please review and update accordingly.	(b) (4), (b) (6)	03 Feb 2021 13:35:07
' (Site from DM).		
User entered 'I'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:23:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:12
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:58:41
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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)	12 Feb 2021 15:58:37
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:58:33
User closed query 'PV Query: Please confirm if aortic root replacement and aortic valve replacement in 2007, cardiac ablation for AVNRT in 2014, and beta hemolytic strep endocarditis in setting of infected molar are medical history are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If any are a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:58:28



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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. ' answered with 'this information has been sent.' (Site from Safety).	Samantha Wheeler (b) (4)	11 Feb 2021 16:12:21
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'medications were added including metoprolol and plavix' (Site from Safety).	Samantha Wheeler (b) (4)	11 Feb 2021 16:09:56
Query 'PV Query: Please confirm if aortic root replacement and aortic valve replacement in 2007, cardiac ablation for AVNRT in 2014, and beta hemolytic strep endocarditis in setting of infected molar are medical history are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If any are a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' answered with 'This is an SAE' (Site from Safety).	Samantha Wheeler (b) (4)	11 Feb 2021 16:01:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'corrected' (Site from Safety).	Samantha Wheeler (b) (4)	11 Feb 2021 15:59:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT PRESENTED WITH PMH WITH SIGNIFICANT REMOTE CARDIAC HISTORY TO INCLUDE S/P AORTIC ROOT REPLACEMENT AND AORTIC VALVE REPLACEMENT IN 2007, CARDIAC ABLATION FOR AVNRT IN 2014, REMOTE HISTORY OF BETA HEMOLYTIC STREP ENDOCARDITIS IN SETTING OF INFECTED MOLAR WHO PRESENTED TO WFBMC ED ON 01/26 FOR NEAR SYNCOPE. PATIENT STATES HE WAS RUNNING UP THE STAIRS AND FELT DISCOMFORT UNDER R CLAVICLE, WITHOUT CENTRAL CHEST PAIN OR RADIATION OF DISCOMFORT. PATIENT STARTED TO FEEL DIZZY, LIGHT HEADED, AND BEGAN TO LOSE PERIPHERAL VISION. PATIENT WAS ABLE TO MAKE IT TO HIS COUCH BEFORE PASSING OUT. PT STATES THIS HAS NEVER HAPPENED BEFORE. PATIENT EXTREMELY MEDICALLY LITERATE AND SHOWS EXCEPTIONAL INSIGHT TO SYMPTOMS. NO HISTORY OF IVDU. DENIES HA, CURRENT VISION CHANGES, ANGINA, PALPITATIONS, PLEURITIC CHEST PAIN, ABDOMINAL PAIN, ABDOMINAL BLOATING, NAUSEA, VOMITING, DIARRHEA, CONSTIPATION, PERIPHERAL EDEMA, FEVER, CHILLS. ENDORSES DIZZINESS AND "FEELING DIFFERENT" THAN HIS BASELINE. No Covid testing was performed prior to this procedure.' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	11 Feb 2021 15:58:50
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)	09 Feb 2021 14:41:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:40:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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)	09 Feb 2021 14:40:50
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)	09 Feb 2021 14:39:47
User opened query 'PV Query: Please confirm if aortic root replacement and aortic valve replacement in 2007, cardiac ablation for AVNRT in 2014, and beta hemolytic strep endocarditis in setting of infected molar are medical history are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If any are a new finding, please assess whether it meets criteria for separate AE/SAE reporting. ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 14:39:31
User entered 'Patient presented with PMH with significant remote cardiac history to include s/p aortic root replacement and aortic valve replacement in 2007, cardiac ablation for AVNRT in 2014, remote history of beta hemolytic strep endocarditis in setting of infected molar who presented to WFBMC ED on 01/26 for near syncope. Patient states he was running up the stairs and felt discomfort under R clavicle, without central chest pain or radiation of discomfort. Patient started to feel dizzy, light headed, and began to lose peripheral vision. Patient was able to make it to his couch before passing out. Pt states this has never happened before. Patient extremely medically literate and shows exceptional insight to symptoms. No history of IVUDU. Denies HA, current vision changes, angina, palpitations, pleuritic chest pain, abdominal pain, abdominal bloating, nausea, vomiting, diarrhea, constipation, peripheral edema, fever, chills. Endorses dizziness and "feeling different" than his baseline.'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 17:45:20

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Feb 2021 17:45:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Feb 2021 17:45:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Feb 2021 17:45:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:40:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:36:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:15:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:24:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:07:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 16:07:41
Data point term sent to Coder Coding entries removed.	System Kaitlyn Van Leuvan	06 Jan 2021 16:06:30 06 Jan 2021 16:06:12
User entered 'Metoprolol' reason for change: Data Entry Error	(b) (4) Kaitlyn Van Leuvan	06 Jan 2021 16:06:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 09:04:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 09:04:11
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	25 Oct 2020 19:49:56 25 Oct 2020 19:48:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 18:08:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:08:55

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	26 Aug 2020 14:26:10
User entered 'Metoprolol'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:11:02
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	06 Jan 2021 16:05:07
User entered 'No (N)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	06 Jan 2021 16:05:00
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 16:10:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than AORTIC VALVE. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:02:30
User closed query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:33:18
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than AORTIC VALVE. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:49:06
Query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:49:00
User entered 'hypertension' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Oct 2020 19:48:55
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than AORTIC VALVE. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:35:06
User opened query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:34:37
User entered 'HBP/Aortic valve'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '50'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'twice daily (BID)'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:25:54



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per CDM re-query: Site response is noted; however, please consider updating the date format to dd MMM yyyy for lines 1-6. Currently, the DAY and YEAR are provided and the month is UNK. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 16:49:09
Query 'Per CDM re-query: Site response is noted; however, please consider updating the date format to dd MMM yyyy for lines 1-6. Currently, the DAY and YEAR are provided and the month is UNK. Thank you.' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:38:09
User entered 'un UNK 2006' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:38:02
Query 'Per CDM re-query: Site response is noted; however, please consider updating the date format to dd MMM yyyy. Currently, the DAY and YEAR are provided and the month is UNK. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 20:18:42
User opened query 'Per CDM re-query: Site response is noted; however, please consider updating the date format to dd MMM yyyy for lines 1-6. Currently, the DAY and YEAR are provided and the month is UNK. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:59:18
User opened query 'Per CDM re-query: Site response is noted; however, please consider updating the date format to dd MMM yyyy. Currently, the DAY and YEAR are provided and the month is UNK. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:57:46
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2007). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:57:46

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2007). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'correct per source' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 17:24:12
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2007). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 16:10:19
User entered '01 UNK 2006'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)' reason for change: Data Entry Error	Kaitlyn Van Leuvan	01 Feb 2021 21:40:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '30 Jan 2021' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Feb 2021 15:26:03
	(b) (4)	
User entered '29 Jan 2021' reason for change: Data Entry Error	Kaitlyn Van Leuvan	01 Feb 2021 21:40:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:25:54



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User entered '2'	System	26 Aug 2020 14:25:54

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User entered '1'	System	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:03
User entered '804 (804)'	System	26 Aug 2020 14:25:54

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE, PRODUCTSYNONYM: HCT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:49:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 08:49:15
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	25 Oct 2020 19:49:55 25 Oct 2020 19:49:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Aug 2020 15:10:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 15:10:47
Data point term sent to Coder User entered 'HCT Hydrochlorothiazide'	System (b) (4), (b) (6)	26 Aug 2020 14:28:15 26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:11:14
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	06 Jan 2021 16:06:41
User entered 'No (N)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	06 Jan 2021 16:06:33
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 16:12:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:35:51
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:49:32
	(b) (4)	
User entered 'hypertension' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Oct 2020 19:49:27
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:35:33
User entered 'diuretic'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '25'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 14:27:49



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '01 UNK 2018'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:27:49



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:27:49

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:27:49

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 19:51:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 19:51:35
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	25 Oct 2020 19:50:56 25 Oct 2020 19:50:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Aug 2020 14:58:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:58:45
Data point term sent to Coder User entered 'Losartan'	System (b) (4), (b) (6)	26 Aug 2020 14:29:19 26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Prophylaxis=Yes. Please review if this option should be changed as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:36:10
Query 'Per DM CLR: Prophylaxis=Yes. Please review if this option should be changed as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:50:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Oct 2020 19:50:08
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis=Yes. Please review if this option should be changed as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:35:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:36:22
Query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:50:20
	(b) (4)	
User entered 'Hypertension' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Oct 2020 19:50:08
	(b) (4)	
User opened query 'Per DM CLR: Please review the indication and spell out the abbreviation as it should not be used. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:35:48
User entered 'HBP'	(b) (4), (b) (6)	26 Aug 2020 14:28:34



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '100'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '01 UNK 2020'	(b) (4), (b) (6)	26 Aug 2020 14:28:34



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:28:34

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:28:34

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 19:51:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 19:51:35
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	25 Oct 2020 19:50:58 25 Oct 2020 19:50:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Aug 2020 14:57:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:57:49
Data point term sent to Coder User entered 'Lovastatin'	System (b) (4), (b) (6)	26 Aug 2020 14:30:21 26 Aug 2020 14:29:22



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:11:24
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	06 Jan 2021 16:07:00
User entered 'No (N)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	06 Jan 2021 16:06:54
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 16:12:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:37:03
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:51:00
	(b) (4)	
User entered 'high cholesterol' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Oct 2020 19:50:44
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:36:14
User entered 'Cholesterol management'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '40'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:29:22

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 14:29:22



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '01 UNK 2006'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 15:50:00
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'condition is ongoing ' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 17:23:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 16:14:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:29:22

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:29:22

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:29:22



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:29:22

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
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.	Coder Import (b) (4)	26 Oct 2020 08:47:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 08:47:35
Data point term sent to Coder	System	25 Oct 2020 19:51:59
Coding entries removed.	Samantha Wheeler (b) (4)	25 Oct 2020 19:51:51
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.	Coder Import (b) (4)	27 Aug 2020 17:48:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:48:12
Data point term sent to Coder	System	26 Aug 2020 14:30:24
User entered 'Aspirin'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:37:24
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	25 Oct 2020 19:51:57
User entered 'supplement for heart health' reason for change: Data Entry Error	(b) (4)	25 Oct 2020 19:51:51
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 11:36:28
User entered 'Aortic valve'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '325'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 14:30:19



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '01 UNK 2006'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:27:50
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Un-verified.	Kaitlyn Van Leuvan	29 Mar 2021 12:38:12
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kaitlyn Van Leuvan	29 Mar 2021 12:38:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:27:50
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	29 Mar 2021 12:38:12
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	29 Mar 2021 12:37:56
DataPoint Un-verified.	Kaitlyn Van Leuvan	29 Mar 2021 12:37:56
	(b) (4)	
User entered '30 Jan 2021' reason for change: Data Entry Error	Kaitlyn Van Leuvan	29 Mar 2021 12:37:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:30:19



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User entered '1'	System	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User entered '1'	System	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:40:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:55:12
User entered '804 (804)'	System	26 Aug 2020 14:30:19

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTS YNonym: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:32:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:32:55
Data point term sent to Coder	System	26 Aug 2020 14:32:26
User entered 'Multi Vitamin'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Supplement'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per CDM: As per CCGs p. 36, If dose is unknown, enter "UNK" into the text field. Please change UNKNOWN to UNK to be consistent with the CCGs.	(b) (4), (b) (6)	26 Oct 2020 17:48:38
' (Site from DM).		
Query 'Per CDM: As per CCGs p. 36, If dose is unknown, enter "UNK" into the text field. Please change UNKNOWN to UNK to be consistent with the CCGs.	Samantha Wheeler (b) (4)	25 Oct 2020 19:52:29
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'UNK' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Oct 2020 19:52:22
	(b) (4)	
User opened query 'Per CDM: As per CCGs p. 36, If dose is unknown, enter "UNK" into the text field. Please change UNKNOWN to UNK to be consistent with the CCGs.	(b) (4), (b) (6)	24 Sep 2020 11:34:42
' (Site from DM).		
User entered 'Unknown'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Aug 2020 14:31:27



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Unknown'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '01 UNK 2006'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 14:31:27



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 14:31:27

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 14:31:27

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 14:31:27

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 21:40:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 21:40:37
Data point term sent to Coder	System	01 Feb 2021 21:39:57
User entered 'Metoprolol'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Hypertension'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '25'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'twice daily (BID)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '30 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 21:39:45

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Feb 2021 21:39:45

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
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 BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 19:34:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 19:34:01
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 19:32:57
Coding entries removed.	(b) (4), (b) (6)	22 Feb 2021 19:32:31
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 BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:42:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Feb 2021 21:42:32
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 21:42:04
User entered 'Plavix'	Kaitlyn Van Leuvan	01 Feb 2021 21:41:07
	(b) (4)	



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	23 Feb 2021 22:59:18
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	22 Feb 2021 19:32:43
' answered with 'indication updated per medical history ' (Site from DM).		
User entered 'Aortic Aneurysm' reason for change:	(b) (4), (b) (6)	22 Feb 2021 19:32:31
Data Entry Error		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	21 Feb 2021 13:42:29
' (Site from DM).		
User entered 'antiplatelet'	Kaitlyn Van Leuvan	01 Feb 2021 21:41:07
	(b) (4)	

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '75'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:40:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) John Sanders (b) (4)	16 Apr 2021 09:39:15 12 Apr 2021 17:16:21
Query 'Per CDM RQ: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Medication was prescribed per subject after initial AE.' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	08 Apr 2021 17:42:54
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:57:17
User opened query 'Per CDM RQ: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:57:07
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Correct per patient, prescribed after initial AE.' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	08 Mar 2021 13:37:46
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:57:14
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '31 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 21:41:07

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 21:41:07



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Feb 2021 21:41:07

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this medication overlaps with CM #5. Please reconcile and confirm if these are both ongoing. Review and update Con Med start/stop dates if applicable. Otherwise, provide explanation.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 09:39:20
Query 'Per DM CLR: Please note this medication overlaps with CM #5. Please reconcile and confirm if these are both ongoing. Review and update Con Med start/stop dates if applicable. Otherwise, provide explanation.' answered with 'Updated the conmed #5 with a stop date.' (Site from DM).	John Sanders (b) (4)	12 Apr 2021 17:16:21
User opened query 'Per DM CLR: Please note this medication overlaps with CM #5. Please reconcile and confirm if these are both ongoing. Review and update Con Med start/stop dates if applicable. Otherwise, provide explanation.' (Site from DM). DataPoint Verified.	Kaitlyn Van Leuvan (b) (4)	29 Mar 2021 12:39:37
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), (b) (6)	18 Mar 2021 01:30:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	25 Feb 2021 19:47:38
Data point term sent to Coder User entered 'aspirin'	Coder Import (b) (4)	25 Feb 2021 15:27:54
	(b) (4)	
	System	25 Feb 2021 15:27:25
	Samantha Wheeler (b) (4)	25 Feb 2021 15:27:01
	(b) (4)	

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'aortic valve'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '81'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'mg (mg)'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'once daily (QD)'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01



US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '30 Jan 2021'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered '0'	Samantha Wheeler (b) (4)	25 Feb 2021 15:27:01
	(b) (4)	

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:40:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:38
User entered 'No (N)'	Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:27:01



**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 15:27:01

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 15:27:01

**US3762023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:40:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 15:27:01

US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:40:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:36:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:28:40
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wheeler (b) (4)	11 Feb 2021 16:03:31
User entered 'No (N)'	(b) (4)	
	Samantha Wheeler (b) (4)	09 Feb 2021 18:03:18
	(b) (4)	

US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:12
User entered '28 Jan 2021'	Samantha Wheeler (b) (4) (b) (4)	11 Feb 2021 16:04:48

US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:12
User entered 'CT Angiography of the heart'	Samantha Wheeler (b) (4) (b) (4)	11 Feb 2021 16:04:48

US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:12
User entered 'Adverse Event (AE)'	Samantha Wheeler (b) (4) (b) (4)	11 Feb 2021 16:04:48

US3762023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:40:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:16:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:47:12
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	11 Feb 2021 16:04:48



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered		
'USA-US130-2021-MRNA-1273-P301000004'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Yes (Y)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Yes (Y)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'John'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Sanders'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered '100 Medical Center Blvd'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Winston-Salem'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'NC'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered '27157'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:59:37
User entered 'US'	System	02 Feb 2021 15:46:15

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Feb 2021 15:59:50
User entered '1'	System	02 Feb 2021 15:46:15



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered		
'USA-US130-2021-MRNA-1273-P301000004'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Yes (Y)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Yes (Y)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'John'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Sanders'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered '100 Medical Center Blvd'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Winston-Salem'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'NC'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered '27157'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:59:37
User entered 'US'	System	02 Feb 2021 15:46:15

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Feb 2021 15:59:50
User entered '1'	System	02 Feb 2021 15:46:15



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:40:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
User entered '02/Feb/2021 15:46'	System	02 Feb 2021 15:46:15

US3762023

Folder: SAE USA-US130-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:40:55

**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.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:59:37
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 15:46:15

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered		
'USA-US130-2021-MRNA-1273-P301000004'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Yes (Y)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Yes (Y)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'No (N)'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'John'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Sanders'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered '100 Medical Center Blvd'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'Winston-Salem'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered 'NC'	System	02 Feb 2021 15:45:49

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:46:07
User entered '27157'	System	02 Feb 2021 15:45:49



**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 15:59:37
User entered 'US'	System	02 Feb 2021 15:46:15

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:40:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Feb 2021 15:59:50
User entered '1'	System	02 Feb 2021 15:46:15

**US3762023**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:40:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:14:29
User entered '12/Feb/2021 15:59'	System	12 Feb 2021 15:59:50

US3762023

Folder: SAE USA-US130-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:40:55

**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.	John Sanders (b) (4)	12 Apr 2021 17:18:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:14:29
User entered 'I'	(b) (4), (b) (6)	12 Feb 2021 15:59:50