

US3762131 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:42:38

All time stamps listed in this document are displayed in GMT

US3762131

Form: Participant Creation

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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Participant ID

US3762131

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

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US3762131

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	48
Age Units	YEARS
Age (Derived)	49
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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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 23:00:15

Generated On: 10 Jun 2021 09:42:38

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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 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	01 UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	ASTHMA
Start date (dd MMM yyyy)	01 UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	ANXIETY
Start date (dd MMM yyyy)	01 UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	SHINGLES
Start date (dd MMM yyyy)	03 UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	03 UNK 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	IRREGULAR PERIODS
Start date (dd MMM yyyy)	09 UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	MILD CONTACT DERMATITIS ON LEG
Start date (dd MMM yyyy)	31 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	TENDINITIS RIGHT SHOULDER
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
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 23:00:15

Generated On: 10 Jun 2021 09:42:38

Condition	LEG CRAMPS
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 09:48
Height (xxx.x)	67 in
Weight (xxx.x)	200 lb
BMI (xxx.x)	31.38992 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 23:00:15

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Date of assessment (*dd MMM yyyy*) 1 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	1 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:00:15

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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>	True
<b>Specify</b>	INTERACTS WITH MORE THAN 5 PEOPLE DURING THE COURSE OF A TYPICAL WORKDAY. ROUTINELY GOES TO PLACES WHERE PEOPLE GATHER. PATIENT ATTENDED A LARGE GROUP EVENT IN THE PAST FEW WEEKS.



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110529

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 23:00:15

Generated On: 10 Jun 2021 09:42:38

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 23:00:15

Generated On: 10 Jun 2021 09:42:38

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)	1 SEP 2020
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 09:48
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 11:16
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 10:41

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 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	10:21 (24 HR)
Collection date and time (derived)	1 SEP 2020 10:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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 09:42:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

01 SEP 2020 11:23

PC Open Date & Time

01 SEP 2020 11:01

PC Close Date & Time

01 SEP 2020 13:31

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	01 SEP 2020 17:19
PC Open Date & Time	01 SEP 2020 14:26
PC Close Date & Time	02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

02 SEP 2020 13:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:34

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

04 SEP 2020 18:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

05 SEP 2020 16:05

---

PC Open Date & Time

05 SEP 2020 12:00

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PC Close Date & Time

06 SEP 2020 11:59

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US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**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

06 SEP 2020 18:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**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

98.8 °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

07 SEP 2020 13:51

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 11:20

PC Open Date & Time

01 SEP 2020 11:01

PC Close Date & Time

01 SEP 2020 13:31

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**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

01 SEP 2020 16:42

PC Open Date & Time

01 SEP 2020 14:26

PC Close Date & Time

02 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**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

02 SEP 2020 13:21

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**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

03 SEP 2020 12:21

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**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

04 SEP 2020 18:25

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**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

05 SEP 2020 14:08

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**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

06 SEP 2020 17:59

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**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

07 SEP 2020 13:52

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**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 ☐

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 11:21
PC Open Date & Time	01 SEP 2020 11:01
PC Close Date & Time	01 SEP 2020 13:31

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**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 ☐

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 16:42
PC Open Date & Time	01 SEP 2020 14:26
PC Close Date & Time	02 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**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 ☒



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:21
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 ☒

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:21
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 ☒

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:24
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 14:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 ☒



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 17:58
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 ☒

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:52
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762131

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3762131

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3762131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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)	29 SEP 2020
Time of assessment (00:00-23:59)	09:18 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:18
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3762131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:30
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3762131

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3762131

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	29 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3762131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 9:54 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 9:54

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

What was the frequency of the study treatment dosing? ONCE

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

US3762131

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

29 SEP 2020 09:27



US3762131

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:31	29 SEP 2020 09:31
Nasopharyngeal Swab 2	No		

US3762131

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

29 SEP 2020 10:33

PC Open Date & Time

29 SEP 2020 10:14

PC Close Date & Time

29 SEP 2020 12:44

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**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 99.3 °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	29 SEP 2020 17:08
PC Open Date & Time	29 SEP 2020 13:39
PC Close Date & Time	30 SEP 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**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

100.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 SEP 2020 13:08

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	01 OCT 2020 19:26
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 OCT 2020 15:10

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 03 OCT 2020 19:46

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**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

97.7 °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

04 OCT 2020 19:57

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**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

98.6 °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

05 OCT 2020 20:50

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 10:33

PC Open Date & Time

29 SEP 2020 10:14

PC Close Date & Time

29 SEP 2020 12:44

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

20

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

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

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

29 SEP 2020 18:26

PC Open Date & Time

29 SEP 2020 13:39

PC Close Date & Time

30 SEP 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 13:05

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**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

01 OCT 2020 19:27

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**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

02 OCT 2020 15:10

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**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

03 OCT 2020 19:47

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**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

04 OCT 2020 18:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**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

05 OCT 2020 14:20

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**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 ☐

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:34
PC Open Date & Time	29 SEP 2020 10:14
PC Close Date & Time	29 SEP 2020 12:44

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**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 ☐

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 16:05
PC Open Date & Time	29 SEP 2020 13:39
PC Close Date & Time	30 SEP 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**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 ☒

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 13:04
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**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 ☒

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 19:27
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 15:10
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 ☒

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:47
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

110 of 2160

EAB) (1725)

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 ☒

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 14:20
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3762131

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3762131

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3762131

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 09:12
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762131

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

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.*

US3762131

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

09:19 (24 HR)

Collection date and time (derived)

27 OCT 2020 09:19

US3762131

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:00:15

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

03 NOV 2020 09:59:04

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

11 NOV 2020 04:49:23

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

17 NOV 2020 08:34:00

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59



US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 NOV 2020 19:35:11
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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	03 DEC 2020 09:34:16
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

10 DEC 2020 09:33:55

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

17 DEC 2020 07:12:36

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

24 DEC 2020 14:04:21

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

14 JAN 2021 14:14:04

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 13:05:45

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

28 JAN 2021 08:34:38

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

04 FEB 2021 08:41:13

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 10:09:50

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59



US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 FEB 2021 09:04:43
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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	25 FEB 2021 09:51:05
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

06 MAR 2021 14:35:02

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

13 MAR 2021 12:39:41

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 07:38:37

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

25 MAR 2021 06:16:06

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

01 APR 2021 08:32:15

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

08 APR 2021 07:31:52

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59



US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

15 APR 2021 07:09:14

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

22 APR 2021 01:54:32

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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

29 APR 2021 00:02:11

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	11 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2022 23:59
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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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="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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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19 SEP 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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 <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"/>

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

**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 ☐

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59

US3762131

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

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"/>



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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**US3762131**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:42:38**

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		06 MAR 2021 14:35:14

US3762131

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 18:30:39

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 18:30:38

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3762131

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3762131

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762131

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

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

Visit date (dd MMM yyyy)	30 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
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US3762131

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3762131

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

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.*

US3762131

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	10:05 (24 HR)
Collection date and time (derived)	30 MAR 2021 10:05

US3762131

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:23:16

Generated On: 10 Jun 2021 09:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3762131**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

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*



**US3762131**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3762131**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:42:38**

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"/>

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3762131

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3762131

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Date of updated informed consent (dd MMM yyyy) 14 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 14 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3762131

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	14:22 (24 HR)
Collection date and time (derived)	14 JAN 2021 14:22

US3762131

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	14:26
Collection Date and Time (derived)	14 JAN 2021 14:26

US3762131

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Mar 2021 17:29:05

Generated On: 10 Jun 2021 09:42:38

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3762131

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

AEID	
Adverse event	DERMATITIS WORSENING
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3762131

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

AEID	USA-US130-2021-MRNA-1273-P30 1000006
Adverse event	CLOSED DISPLACED PILON FRACTURE OF RIGHT TIBIA
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)	20 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 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 (2)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3762131

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

---

COMMINUTED FRACTURES OF  
THE DISTAL TIBIA; DISTAL  
FIBULAR FRACTURE WHICH  
EXTENDS TO THE LATERAL  
MALLEOLUS. POSTERIOR  
DISPLACEMENT AND SLIGHT  
VALGUS DEFORMITY OF THE  
FIBULA" S/P "CLOSED  
REDUCTION RIGHT DISTAL  
TIBIA AND FIBULA FRACTURES  
WITH APPLICATION OF ANKLE  
SPANNING EXTERNAL  
FIXATOR. PATIENT SUSTAINED  
THIS INJURY FROM A FALL  
DOWN A SLIDE. CBC DRAWN  
3/21/2021 SHOWS WBC 7.3, RBC  
3.77, HEMOGLOBIN 11.8,  
HEMATOCRIT 35.9. COVID TEST  
WAS NOT PERFORMED PER  
ELECTRONIC MEDICAL  
RECORD.

---

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

---

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

AEID	USA-US130-2021-MRNA-1273-P30 1000006
Adverse event	COMMINUTED DISTAL FIBULAR FRACTURE
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)	20 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 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 (3)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

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

US3762131

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Apr 2021 17:33:57

Generated On: 10 Jun 2021 09:42:38

---

COMMINUTED FRACTURES OF  
THE DISTAL TIBIA; DISTAL  
FIBULAR FRACTURE WHICH  
EXTENDS TO THE LATERAL  
MALLEOLUS. POSTERIOR  
DISPLACEMENT AND SLIGHT  
VALGUS DEFORMITY OF THE  
FIBULA" S/P "CLOSED  
REDUCTION RIGHT DISTAL  
TIBIA AND FIBULA FRACTURES  
WITH APPLICATION OF ANKLE  
SPANNING EXTERNAL  
FIXATOR. PATIENT SUSTAINED  
THIS INJURY FROM A FALL  
DOWN A SLIDE. CBC DRAWN  
3/21/2021 SHOWS WBC 7.3, RBC  
3.77, HEMOGLOBIN 11.8,  
HEMATOCRIT 35.9. COVID TEST  
WAS NOT PERFORMED PER  
ELECTRONIC MEDICAL  
RECORD.

---

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

---



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

---

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

Yes ☒

No ☐

---

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

---

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication OMEGA 3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication MONOCAL  
[MONOFLUOROPHOSPHATE,  
CALCIUM CARBONATE]

Prophylaxis Yes ☐  
No ☒

Indication TINNITUS

Dose per administration 22.75 - 625

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication LEGS CRAMPING

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

	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)	06 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication PREDNISONE TAPER

Prophylaxis Yes ☐  
No ☒

Indication DERMATITIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication TURMERIC

Prophylaxis Yes ☐  
No ☒

Indication INFLAMMATION OF THE KNEES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT TIBIA FRACTURE PAIN

Dose per administration 650

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

Q6 HR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication ASA

Prophylaxis Yes ☒  
No ☐

Indication POST OPERATIVE BLOOD CLOT  
PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication FENTANYL CITRATE

Prophylaxis Yes ☐  
No ☒

Indication LEG FRACTURE PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication LEG FRACTURE PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3762131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3762131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
20 MAR 2021	CLOSED REDUCTION AND LOWER EXTREMITY EXTERNAL FIXATOR APPLICATION RIGHT TIBIA	Adverse Event	
22 MAR 2021	REMOVE EXTERNAL FIXATOR, REMOVE ANKLE SCREWS, ORIF FIBULA AND TIBIA WITH INSERTION IM NAIL	Adverse Event	

US3762131

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:42:38

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



US3762131

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:42:38

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 ☐

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

SAEID	USA-US130-2021-MRNA-1273-P301000006
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)	4

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

SAEID	USA-US130-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

SAEID	USA-US130-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	29/MAR/2021 10:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

SAEID	USA-US130-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	31/MAR/2021 09:47
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

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 18:23:15

Generated On: 10 Jun 2021 09:42:38

SAEID	USA-US130-2021-MRNA-1273-P301000006
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)	4
Date of submission (Pre-filled from custom function)	07/APR/2021 08:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3762131 (Prod: Wake Forest University Health Sciences)

**US3762131**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:42:38**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:46:53
User entered 'US3762131'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:36



**US3762131**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:35:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:04:55

**US3762131**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 15:35:37
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:37

**US3762131**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:35:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 15:04:55

**US3762131**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'SCRN'	System	01 Sep 2020 15:04:55

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered (b) (6) 1971'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:38

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '48'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'YEARS'	System	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '49'	System	01 Sep 2020 15:05:17



**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered 'Female (F)'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30



**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:42:38**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:00
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:52:30

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Sep 2020'	System	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2020'	System	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:05:17



**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:05:17

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:10
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:37

**US3762131**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:42:38**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'I'	System	01 Sep 2020 15:05:36

**US3762131**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:42:38**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:36:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:05:36

**US3762131**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:42:38**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:37:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:53:05

US3762131

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:55:40
Data point term sent to Coder	System	02 Sep 2020 14:54:50
User entered 'seasonal allergies'	(b) (4), (b) (6)	02 Sep 2020 14:53:58



**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '01 UNK 1995'	(b) (4), (b) (6)	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 1995'	System	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '1995'	System	02 Sep 2020 14:53:58

**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:53:58



**US3762131**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:53:58

US3762131

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:55:40
Data point term sent to Coder	System	02 Sep 2020 14:54:50
User entered 'asthma'	(b) (4), (b) (6)	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '01 UNK 2005'	(b) (4), (b) (6)	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2005'	System	02 Sep 2020 14:54:27



**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2005'	System	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:54:27

**US3762131**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:54:27

US3762131

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:56:45
Data point term sent to Coder	System	02 Sep 2020 14:55:51
User entered 'anxiety'	(b) (4), (b) (6)	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '01 UNK 2009'	(b) (4), (b) (6)	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:54:55



**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2009'	System	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2009'	System	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:54:55

**US3762131**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:54:55

US3762131

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
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) (b) (4)	02 Sep 2020 14:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:56:45
Data point term sent to Coder	System	02 Sep 2020 14:55:51
User entered 'shingles'	(b) (4), (b) (6)	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '03 UNK 2020'	(b) (4), (b) (6)	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:55:42



**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '03 UNK 2020'	(b) (4), (b) (6)	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2020'	System	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2020'	System	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2020'	System	02 Sep 2020 14:55:42

**US3762131**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2020'	System	02 Sep 2020 14:55:42

US3762131

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Menstruation irregular, LLT: Irregular periods - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:57:43
Data point term sent to Coder	System	02 Sep 2020 14:56:55
User entered 'irregular periods'	(b) (4), (b) (6)	02 Sep 2020 14:56:08



**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '09 UNK 2019'	(b) (4), (b) (6)	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2019'	System	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2019'	System	02 Sep 2020 14:56:08

**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:56:08



**US3762131**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:56:08

US3762131

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:42:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:25:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:25:43
Data point term sent to Coder	System	02 Oct 2020 19:55:24
User entered 'mild contact dermatitis on leg'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '31 Aug 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Aug 2020'	System	02 Oct 2020 19:54:25



**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2020'	System	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Oct 2020 19:54:25

**US3762131**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Oct 2020 19:54:25

US3762131

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:42:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:29:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:29:01
Data point term sent to Coder	System	13 Oct 2020 13:28:25
User entered 'vitamin d deficiency'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'un UNK 2014'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:27:24



**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2014'	System	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2014'	System	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	13 Oct 2020 13:27:24

**US3762131**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	13 Oct 2020 13:27:24

US3762131

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
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) (b) (4)	13 Oct 2020 13:31:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:31:33
Data point term sent to Coder	System	13 Oct 2020 13:30:29
User entered 'tinnitus'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'un UNK 2005'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:30:25



**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:40:04
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2005'	System	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2005'	System	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	13 Oct 2020 13:30:25

**US3762131**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	13 Oct 2020 13:30:25

US3762131

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint swelling, LLT: Swelling of knees - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:56:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:56:37
Data point term sent to Coder	System	24 Nov 2020 14:51:05
User entered 'Inflammation of Knees'	(b) (4), (b) (6)	24 Nov 2020 14:50:16



**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered 'UN UNK 2015'	(b) (4), (b) (6)	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2015'	System	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2015'	System	24 Nov 2020 14:50:16

**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	24 Nov 2020 14:50:16



**US3762131**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	24 Nov 2020 14:50:16

US3762131

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Shoulder tendinitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 19:34:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 19:34:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:02:33
Data point term sent to Coder	System	17 Dec 2020 18:39:22
User entered 'tendinitis right shoulder'	Samantha Wheeler (b) (4)	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered 'un UNK 2003'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2003'	System	17 Dec 2020 18:39:07



**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2003'	System	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	17 Dec 2020 18:39:07

**US3762131**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	17 Dec 2020 18:39:07

US3762131

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:42:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:42:47
Data point term sent to Coder	System	17 Dec 2020 18:41:23
User entered 'leg cramps'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered 'un UNK 2020'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:40:31



**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 19:02:33
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'Jan 2020'	System	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '2020'	System	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	17 Dec 2020 18:40:31

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered '09:48'	(b) (4), (b) (6)	02 Sep 2020 14:57:25



**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '1 Sep 2020 09:48'	System	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered '67' in	(b) (4), (b) (6)	02 Sep 2020 14:57:25
DataPoint set to visible.	System	01 Sep 2020 15:05:36

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered '200' lb	(b) (4), (b) (6)	02 Sep 2020 14:57:25
DataPoint set to visible.	System	01 Sep 2020 15:05:36

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '31.38992'	System	02 Sep 2020 14:57:25
DataPoint set to visible.	System	01 Sep 2020 15:05:36

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'kg/m2'	System	02 Sep 2020 14:57:25
DataPoint set to visible.	System	01 Sep 2020 15:05:36

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:57:25



**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'bpm'	System	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'breaths/min'	System	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'mmHg'	System	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 15:58:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 14:57:25

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'mmHg'	System	02 Sep 2020 14:57:25



**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37

**US3762131**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37

**US3762131**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:57:50

**US3762131**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:14
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 14:57:50

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:58:57



**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:42:38**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:28
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 14:58:57

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered 'Urine (URINE)'	(b) (4), (b) (6)	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	02 Sep 2020 14:59:13



**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:59:56
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	02 Sep 2020 14:59:13

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37



US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

[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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:37



**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

US3762131

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:38

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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 15:08:37



**US3762131**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:02
User entered 'Interacts with more than 5 people during the course of a typical workday. Routinely goes to places where people gather. Patient attended a large group event in the past few weeks.'	(b) (4), (b) (6)	01 Sep 2020 15:08:37

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:08:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:13:11
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 15:51:59
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:51:59
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:01:33
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 15:08:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:01:33
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 15:08:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'VISIT1'	System	01 Sep 2020 15:08:55

US3762131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:24:58

US3762131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered '110529'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:24:58

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:42:38**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:24:58



US3762131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:17

US3762131

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:17

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:42:38**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:17

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:42:38**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:17

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:42:38**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:17

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:42:38**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:02:24
User entered 'No (N)'	James Lovette (b) (4)	28 Sep 2020 13:26:11
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:53:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:53:24

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:42:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:42:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 15:01:35



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:42:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:42:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '09:48'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '1 Sep 2020 09:48'	System	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '98.6' F	(b) (4), (b) (6)	02 Sep 2020 15:01:35



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '78'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'bpm'	System	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '15'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'breaths/min'	System	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '117'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Sep 2020 15:01:35



US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '68'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:42:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:42:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '11:16'	(b) (4), (b) (6)	02 Sep 2020 15:01:35



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '1 Sep 2020 11:16'	System	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '98.4' F	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '73'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'bpm'	System	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '16'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'breaths/min'	System	02 Sep 2020 15:01:35



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '116'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:29
User entered '70'	(b) (4), (b) (6)	02 Sep 2020 15:01:35

US3762131

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Sep 2020 15:01:35

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:42
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:01:44

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:03:42
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:01:44

US3762131

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:42:38

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:06:47
Query 'Per CDM: Subject was screened and dosed on Samantha Wheeler the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'Done' (Site from DM).	(b) (4) (b) (4)	21 Sep 2020 01:18:39
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	21 Sep 2020 01:18:31
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 01:40:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	21 Sep 2020 01:18:31
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:02:13



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	21 Sep 2020 01:18:31
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	21 Sep 2020 01:18:31
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:01
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered empty.	System	02 Sep 2020 15:02:13

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:10:07

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:10:07



US3762131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:10:07

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 15:10:07

US3762131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 15:10:07

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered '10:41'	(b) (4), (b) (6)	01 Sep 2020 15:10:07

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '1 Sep 2020 10:41'	System	01 Sep 2020 15:10:07

US3762131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Sep 2020 15:10:07

US3762131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:04:20
User entered 'ONCE'	System	01 Sep 2020 15:10:07

US3762131

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 15:10:07



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:02:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:05
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 15:02:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:05
User entered '10:21'	(b) (4), (b) (6)	02 Sep 2020 15:02:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '1 Sep 2020 10:21'	System	02 Sep 2020 15:02:55

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:15
User entered '1 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:15
User entered '10:18'	(b) (4), (b) (6)	02 Sep 2020 15:03:21



**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '1 Sep 2020 10:18'	System	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:15
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:15
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered empty.	System	02 Sep 2020 15:03:21

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:05:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:03:30

**US3762131**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	02 Sep 2020 15:03:30

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:23:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c7fc516f-4f2b-48da-815d-9cca08a46178'	System	01 Sep 2020 15:23:50
User entered 'Yes (Y)'	System	01 Sep 2020 15:23:50

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:23:39', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c7fc516f-4f2b-48da-815d-9cca08a46178'	System	01 Sep 2020 15:23:50
User entered '98.4'	System	01 Sep 2020 15:23:50

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:23:43', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c7fc516f-4f2b-48da-815d-9cca08a46178'	System	01 Sep 2020 15:23:50
User entered 'No (N)'	System	01 Sep 2020 15:23:50

**US3762131**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:23:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c7fc516f-4f2b-48da-815d-9cca08a46178'	System	01 Sep 2020 15:23:50
User entered '01 Sep 2020 11:23'	System	01 Sep 2020 15:23:50

**US3762131**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 11:01'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 13:31'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T17:19:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0adadb5b-1761-431d-95fb-966f5869bd33'	System	01 Sep 2020 21:19:26
User entered 'Yes (Y)'	System	01 Sep 2020 21:19:26



US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T17:19:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0adadb5b-1761-431d-95fb-966f5869bd33' User entered '97.9'	System	01 Sep 2020 21:19:26

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T17:19:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0adadb5b-1761-431d-95fb-966f5869bd33'	System	01 Sep 2020 21:19:26
User entered 'No (N)'	System	01 Sep 2020 21:19:26

**US3762131**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T17:19:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0adadb5b-1761-431d-95fb-966f5869bd33'	System	01 Sep 2020 21:19:26
User entered '01 Sep 2020 17:19'	System	01 Sep 2020 21:19:26

**US3762131**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 14:26'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 2'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0aff538-fd64-45a4-b888-b2d9c249f083'	System	02 Sep 2020 17:22:56
User entered 'Yes (Y)'	System	02 Sep 2020 17:22:56

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:22:51', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0aff538-fd64-45a4-b888-b2d9c249f083' User entered '98.9'	System	02 Sep 2020 17:22:56
	System	02 Sep 2020 17:22:56



US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:22:54', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0aff538-fd64-45a4-b888-b2d9c249f083'	System	02 Sep 2020 17:22:56
User entered 'No (N)'	System	02 Sep 2020 17:22:56

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:22:57', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0aff538-fd64-45a4-b888-b2d9c249f083'	System	02 Sep 2020 17:22:56
User entered '02 Sep 2020 13:22'	System	02 Sep 2020 17:22:56

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 3'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T16:33:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bbd620-33a4-4d94-b820-ce6fbb316839'	System	03 Sep 2020 20:34:10
User entered 'Yes (Y)'	System	03 Sep 2020 20:34:10

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T16:33:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bbd620-33a4-4d94-b820-ce6fbb316839' User entered '98.9'	System	03 Sep 2020 20:34:10

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T16:34:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bbd620-33a4-4d94-b820-ce6fbb316839'	System	03 Sep 2020 20:34:10
User entered 'No (N)'	System	03 Sep 2020 20:34:10



**US3762131**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T16:34:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bbd620-33a4-4d94-b820-ce6fbb316839'	System	03 Sep 2020 20:34:10
User entered '03 Sep 2020 16:34'	System	03 Sep 2020 20:34:10

**US3762131**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 4'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:45:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e879e570-5a58-4587-9195-a44273e2d0e9'	System	04 Sep 2020 22:46:43
User entered 'Yes (Y)'	System	04 Sep 2020 22:46:43

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:46:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e879e570-5a58-4587-9195-a44273e2d0e9' User entered '98.2'	System	04 Sep 2020 22:46:43

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:46:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e879e570-5a58-4587-9195-a44273e2d0e9'	System	04 Sep 2020 22:46:43
User entered 'No (N)'	System	04 Sep 2020 22:46:43

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:46:41', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e879e570-5a58-4587-9195-a44273e2d0e9'	System	04 Sep 2020 22:46:43
User entered '04 Sep 2020 18:46'	System	04 Sep 2020 22:46:43



US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 5'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T16:04:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3af4132a-42d7-45e2-87f7-8f09b7064dc1'	System	05 Sep 2020 20:05:08
User entered 'Yes (Y)'	System	05 Sep 2020 20:05:08

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T16:04:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3af4132a-42d7-45e2-87f7-8f09b7064dc1' User entered '98.3'	System	05 Sep 2020 20:05:08
	System	05 Sep 2020 20:05:08

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T16:04:30', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3af4132a-42d7-45e2-87f7-8f09b7064dc1'	System	05 Sep 2020 20:05:08
User entered 'No (N)'	System	05 Sep 2020 20:05:08

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T16:05:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3af4132a-42d7-45e2-87f7-8f09b7064dc1'	System	05 Sep 2020 20:05:08
User entered '05 Sep 2020 16:05'	System	05 Sep 2020 20:05:08

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:10:07



**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 6'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T18:00:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '99521fe7-0a69-471a-9a27-4767b62fb84a'	System	06 Sep 2020 22:00:38
User entered 'Yes (Y)'	System	06 Sep 2020 22:00:38

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T18:00:28', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '99521fe7-0a69-471a-9a27-4767b62fb84a' User entered '98.7'	System	06 Sep 2020 22:00:38
	System	06 Sep 2020 22:00:38

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T18:00:31', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '99521fe7-0a69-471a-9a27-4767b62fb84a'	System	06 Sep 2020 22:00:38
User entered 'No (N)'	System	06 Sep 2020 22:00:38

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T18:00:33', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '99521fe7-0a69-471a-9a27-4767b62fb84a'	System	06 Sep 2020 22:00:38
User entered '06 Sep 2020 18:00'	System	06 Sep 2020 22:00:38

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 7'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:51:40', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6464c6ad-ae6d-41fe-b52b-765fe1467899'	System	07 Sep 2020 17:51:54
User entered 'Yes (Y)'	System	07 Sep 2020 17:51:54

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:51:45', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6464c6ad-ae6d-41fe-b52b-765fe1467899'	System	07 Sep 2020 17:51:54
User entered '98.8'	System	07 Sep 2020 17:51:54

US3762131

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:51:48', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6464c6ad-ae6d-41fe-b52b-765fe1467899'	System	07 Sep 2020 17:51:54
User entered 'No (N)'	System	07 Sep 2020 17:51:54

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:51:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6464c6ad-ae6d-41fe-b52b-765fe1467899'	System	07 Sep 2020 17:51:54
User entered '07 Sep 2020 13:51'	System	07 Sep 2020 17:51:54

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:19:51', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd710d8df-4f70-496b-aa7c-61bfba91526'	System	01 Sep 2020 15:20:24
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 15:20:24

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd710d8df-4f70-496b-aa7c-61bfeba91526'	System	01 Sep 2020 15:20:24
User entered 'No (N)'	System	01 Sep 2020 15:20:24

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:10', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd710d8df-4f70-496b-aa7c-61bfeba91526'	System	01 Sep 2020 15:20:24
User entered 'No (N)'	System	01 Sep 2020 15:20:24

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd710d8df-4f70-496b-aa7c-61bfba91526'	System	01 Sep 2020 15:20:24
User entered 'None (1)'	System	01 Sep 2020 15:20:24

**US3762131**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd710d8df-4f70-496b-aa7c-61bfeba91526'	System	01 Sep 2020 15:20:24
User entered '01 Sep 2020 11:20'	System	01 Sep 2020 15:20:24

**US3762131**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 11:01'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 13:31'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:41:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f634efe6-7a0d-4938-adee-8a9107210dee'	System	01 Sep 2020 20:42:05
User entered 'None (1)'	System	01 Sep 2020 20:42:05

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:41:55', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f634efe6-7a0d-4938-adee-8a9107210dee'	System	01 Sep 2020 20:42:05
User entered 'No (N)'	System	01 Sep 2020 20:42:05

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:41:58', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f634efe6-7a0d-4938-adee-8a9107210dee'	System	01 Sep 2020 20:42:05
User entered 'No (N)'	System	01 Sep 2020 20:42:05

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f634efe6-7a0d-4938-adee-8a9107210dee'	System	01 Sep 2020 20:42:05
User entered 'None (1)'	System	01 Sep 2020 20:42:05

**US3762131**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:06', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f634efe6-7a0d-4938-adee-8a9107210dee'	System	01 Sep 2020 20:42:05
User entered '01 Sep 2020 16:42'	System	01 Sep 2020 20:42:05

**US3762131**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 14:26'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 2'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '97a32263-5f25-42f9-b1e8-7653c9ce302c'	System	02 Sep 2020 17:21:37
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:21:37

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:20', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '97a32263-5f25-42f9-b1e8-7653c9ce302c'	System	02 Sep 2020 17:21:37
User entered 'No (N)'	System	02 Sep 2020 17:21:37

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '97a32263-5f25-42f9-b1e8-7653c9ce302c'	System	02 Sep 2020 17:21:37
User entered 'No (N)'	System	02 Sep 2020 17:21:37

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:32', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '97a32263-5f25-42f9-b1e8-7653c9ce302c'	System	02 Sep 2020 17:21:37
User entered 'None (1)'	System	02 Sep 2020 17:21:37

**US3762131**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:35', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '97a32263-5f25-42f9-b1e8-7653c9ce302c'	System	02 Sep 2020 17:21:37
User entered '02 Sep 2020 13:21'	System	02 Sep 2020 17:21:37

**US3762131**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 3'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:22', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '678f91e0-f421-4767-835a-472c14bf5578'	System	03 Sep 2020 16:22:09
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:22:09

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:26', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '678f91e0-f421-4767-835a-472c14bf5578'	System	03 Sep 2020 16:22:09
User entered 'No (N)'	System	03 Sep 2020 16:22:09

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:29', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '678f91e0-f421-4767-835a-472c14bf5578'	System	03 Sep 2020 16:22:09
User entered 'No (N)'	System	03 Sep 2020 16:22:09

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:32', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '678f91e0-f421-4767-835a-472c14bf5578'	System	03 Sep 2020 16:22:09
User entered 'None (1)'	System	03 Sep 2020 16:22:09

**US3762131**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '678f91e0-f421-4767-835a-472c14bf5578'	System	03 Sep 2020 16:22:09
User entered '03 Sep 2020 12:21'	System	03 Sep 2020 16:22:09

**US3762131**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 4'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:58', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66adb03-de8a-41f3-9886-d72e409c9ca2'	System	04 Sep 2020 22:25:12
User entered 'None (1)'	System	04 Sep 2020 22:25:12

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:25:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66adb03-de8a-41f3-9886-d72e409c9ca2'	System	04 Sep 2020 22:25:12
User entered 'No (N)'	System	04 Sep 2020 22:25:12

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:25:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66adb03-de8a-41f3-9886-d72e409c9ca2'	System	04 Sep 2020 22:25:12
User entered 'No (N)'	System	04 Sep 2020 22:25:12

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:25:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66adb03-de8a-41f3-9886-d72e409c9ca2'	System	04 Sep 2020 22:25:12
User entered 'None (1)'	System	04 Sep 2020 22:25:12

**US3762131**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:25:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66adb03-de8a-41f3-9886-d72e409c9ca2'	System	04 Sep 2020 22:25:12
User entered '04 Sep 2020 18:25'	System	04 Sep 2020 22:25:12

**US3762131**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 5'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:08:19', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3dc54e6c-944d-4cc0-8b3b-a6547269c7d4'	System	05 Sep 2020 18:08:44
User entered 'None (1)'	System	05 Sep 2020 18:08:44

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:08:30', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3dc54e6c-944d-4cc0-8b3b-a6547269c7d4'	System	05 Sep 2020 18:08:44
User entered 'No (N)'	System	05 Sep 2020 18:08:44

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:08:33', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3dc54e6c-944d-4cc0-8b3b-a6547269c7d4'	System	05 Sep 2020 18:08:44
User entered 'No (N)'	System	05 Sep 2020 18:08:44

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:08:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3dc54e6c-944d-4cc0-8b3b-a6547269c7d4'	System	05 Sep 2020 18:08:44
User entered 'None (1)'	System	05 Sep 2020 18:08:44

**US3762131**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:08:40', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3dc54e6c-944d-4cc0-8b3b-a6547269c7d4'	System	05 Sep 2020 18:08:44
User entered '05 Sep 2020 14:08'	System	05 Sep 2020 18:08:44

**US3762131**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 6'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:59:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '81043261-0f7e-41de-bfef-1de0a950140d'	System	06 Sep 2020 21:59:24
User entered 'None (1)'	System	06 Sep 2020 21:59:24

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:59:06', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '81043261-0f7e-41de-bfef-1de0a950140d'	System	06 Sep 2020 21:59:24
User entered 'No (N)'	System	06 Sep 2020 21:59:24

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:59:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '81043261-0f7e-41de-bfef-1de0a950140d'	System	06 Sep 2020 21:59:24
User entered 'No (N)'	System	06 Sep 2020 21:59:24

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:59:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '81043261-0f7e-41de-bfef-1de0a950140d'	System	06 Sep 2020 21:59:24
User entered 'None (1)'	System	06 Sep 2020 21:59:24

**US3762131**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:59:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '81043261-0f7e-41de-bfef-1de0a950140d' User entered '06 Sep 2020 17:59'	System	06 Sep 2020 21:59:24
	System	06 Sep 2020 21:59:24

**US3762131**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 7'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:51:55', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ce3c0f18-93b6-4376-9d70-978a3b53a6a2'	System	07 Sep 2020 17:52:10
User entered 'None (1)'	System	07 Sep 2020 17:52:10

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:51:58', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ce3c0f18-93b6-4376-9d70-978a3b53a6a2'	System	07 Sep 2020 17:52:10
User entered 'No (N)'	System	07 Sep 2020 17:52:10

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ce3c0f18-93b6-4376-9d70-978a3b53a6a2'	System	07 Sep 2020 17:52:10
User entered 'No (N)'	System	07 Sep 2020 17:52:10

US3762131

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ce3c0f18-93b6-4376-9d70-978a3b53a6a2'	System	07 Sep 2020 17:52:10
User entered 'None (1)'	System	07 Sep 2020 17:52:10

**US3762131**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ce3c0f18-93b6-4376-9d70-978a3b53a6a2'	System	07 Sep 2020 17:52:10
User entered '07 Sep 2020 13:52'	System	07 Sep 2020 17:52:10

**US3762131**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:10:07



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:35', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'None (0)'	System	01 Sep 2020 15:21:24

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'None (0)'	System	01 Sep 2020 15:21:24

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:20:42', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'None (0)'	System	01 Sep 2020 15:21:24

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:21:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'None (0)'	System	01 Sep 2020 15:21:24

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:21:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'None (0)'	System	01 Sep 2020 15:21:24

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:21:14', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'None (0)'	System	01 Sep 2020 15:21:24

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:21:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered 'No (N)'	System	01 Sep 2020 15:21:24

**US3762131**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T11:21:23', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c0613b46-1eca-4b87-9393-dc8e6fd455ab'	System	01 Sep 2020 15:21:24
User entered '01 Sep 2020 11:21'	System	01 Sep 2020 15:21:24



**US3762131**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 11:01'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 13:31'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:12', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'None (0)'	System	01 Sep 2020 20:42:32

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:15', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'None (0)'	System	01 Sep 2020 20:42:32

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'None (0)'	System	01 Sep 2020 20:42:32

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'None (0)'	System	01 Sep 2020 20:42:32

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'None (0)'	System	01 Sep 2020 20:42:32



**US3762131**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:26', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'None (0)'	System	01 Sep 2020 20:42:32

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:29', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered 'No (N)'	System	01 Sep 2020 20:42:32

**US3762131**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-01T16:42:32', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ead9e710-40ef-478b-a0ee-1a2c5e0aa21b'	System	01 Sep 2020 20:42:32
User entered '01 Sep 2020 16:42'	System	01 Sep 2020 20:42:32

**US3762131**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Sep 2020 14:26'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 2'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:20:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'None (0)'	System	02 Sep 2020 17:21:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:20:52', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'None (0)'	System	02 Sep 2020 17:21:07



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:20:54', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'None (0)'	System	02 Sep 2020 17:21:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:20:57', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'None (0)'	System	02 Sep 2020 17:21:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'None (0)'	System	02 Sep 2020 17:21:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'None (0)'	System	02 Sep 2020 17:21:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered 'No (N)'	System	02 Sep 2020 17:21:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-02T13:21:07', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '61741dcd-51f9-4a4b-a592-d9f63cf30778'	System	02 Sep 2020 17:21:07
User entered '02 Sep 2020 13:21'	System	02 Sep 2020 17:21:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:10:07



**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 3'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:20:29', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'None (0)'	System	03 Sep 2020 16:21:58

**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:20:52', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'None (0)'	System	03 Sep 2020 16:21:58

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:20:48', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'None (0)'	System	03 Sep 2020 16:21:58

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:20:56', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'None (0)'	System	03 Sep 2020 16:21:58

**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:20:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'None (0)'	System	03 Sep 2020 16:21:58

**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'None (0)'	System	03 Sep 2020 16:21:58

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered 'No (N)'	System	03 Sep 2020 16:21:58



**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-03T12:21:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3611882-4af2-4075-a61d-4dac0299d5fb'	System	03 Sep 2020 16:21:58
User entered '03 Sep 2020 12:21'	System	03 Sep 2020 16:21:58

**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 4'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'None (0)'	System	04 Sep 2020 22:24:56

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'None (0)'	System	04 Sep 2020 22:24:56

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:40', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'None (0)'	System	04 Sep 2020 22:24:56

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:42', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'None (0)'	System	04 Sep 2020 22:24:56



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:45', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'None (0)'	System	04 Sep 2020 22:24:56

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'None (0)'	System	04 Sep 2020 22:24:56

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered 'No (N)'	System	04 Sep 2020 22:24:56

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-04T18:24:53', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '87ccbec4-d24b-404d-b2d5-e3cefdc24555'	System	04 Sep 2020 22:24:56
User entered '04 Sep 2020 18:24'	System	04 Sep 2020 22:24:56

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 5'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'None (0)'	System	05 Sep 2020 18:08:18



**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:40', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'None (0)'	System	05 Sep 2020 18:08:18

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:42', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'None (0)'	System	05 Sep 2020 18:08:18

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:46', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'None (0)'	System	05 Sep 2020 18:08:18

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:48', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'None (0)'	System	05 Sep 2020 18:08:18

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:51', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'None (0)'	System	05 Sep 2020 18:08:18

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:07:55', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered 'No (N)'	System	05 Sep 2020 18:08:18

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-05T14:08:14', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '34b69f70-81ee-4617-b56e-74b1fd7b8b1f'	System	05 Sep 2020 18:08:18
User entered '05 Sep 2020 14:08'	System	05 Sep 2020 18:08:18

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:10:07



**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 6'	System	01 Sep 2020 15:10:07

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'None (0)'	System	06 Sep 2020 21:59:02

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:19', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'None (0)'	System	06 Sep 2020 21:59:02

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'None (0)'	System	06 Sep 2020 21:59:02

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'None (0)'	System	06 Sep 2020 21:59:02

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'None (0)'	System	06 Sep 2020 21:59:02

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'None (0)'	System	06 Sep 2020 21:59:02



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:57', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered 'No (N)'	System	06 Sep 2020 21:59:02

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-06T17:58:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c6d18616-d862-4a0f-afe6-01f9f7c884d7'	System	06 Sep 2020 21:59:02
User entered '06 Sep 2020 17:58'	System	06 Sep 2020 21:59:02

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 7'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'None (0)'	System	07 Sep 2020 17:52:33

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:15', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'None (0)'	System	07 Sep 2020 17:52:33

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'None (0)'	System	07 Sep 2020 17:52:33



US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:20', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'None (0)'	System	07 Sep 2020 17:52:33

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:22', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'None (0)'	System	07 Sep 2020 17:52:33

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'None (0)'	System	07 Sep 2020 17:52:33

US3762131

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered 'No (N)'	System	07 Sep 2020 17:52:33

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-07T13:52:30', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0da75653-33fa-4239-8dfb-a2a7635dbd75'	System	07 Sep 2020 17:52:33
User entered '07 Sep 2020 13:52'	System	07 Sep 2020 17:52:33

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:10:07

**US3762131**

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

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:10:07

**US3762131**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:07:54
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:40:37



**US3762131**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:07:54
User entered '09 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:40:37

**US3762131**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:07:54
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:40:37

**US3762131**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:07:54
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:40:37

**US3762131**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:08:02
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:40:46

**US3762131**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	21 Sep 2020 13:40:46

**US3762131**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:08:38
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:42:46

**US3762131**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:08:38
User entered '17 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:42:46

**US3762131**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:08:38
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:42:46



**US3762131**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:08:38
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:42:46

**US3762131**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:09:16
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:42:55

**US3762131**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	21 Sep 2020 13:42:55

**US3762131**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:34:44
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Sep 2020 16:50:26

**US3762131**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:34:44
User entered '22 Sep 2020'	Kaitlyn Van Leuvan (b) (4)	22 Sep 2020 16:50:26

**US3762131**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:34:44
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	22 Sep 2020 16:50:26

**US3762131**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:34:44
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Sep 2020 16:50:26

**US3762131**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:34:48
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Sep 2020 16:50:38



**US3762131**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	22 Sep 2020 16:50:38

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:35:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:12:13

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:35:25
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:12:13

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:35:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 14:12:13

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'VISIT2'	System	29 Sep 2020 14:12:13

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Pre-Dose (PREDOSE)'	James Lovette (b) (4)	02 Oct 2020 19:50:01
	(b) (4)	

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '29 Sep 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01



**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '09:18'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '29 Sep 2020 09:18'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '99.0' F	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered 'Oral (Oral)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered empty.	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '76'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'bpm'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '16'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01



US3762131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'breaths/min'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '116'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '70'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Oct 2020 19:50:01

US3762131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Post-Dose (POSTDOSE)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '29 Sep 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01



**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '10:30'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '29 Sep 2020 10:30'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '98.2' F	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered 'Oral (Oral)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered empty.	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '60'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'bpm'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '16'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01



US3762131

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'breaths/min'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '113'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:16
User entered '70'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	02 Oct 2020 19:50:01

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:20
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:26

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:20
User entered '29 Sep 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:50:26

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02



**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered '29 Sep 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered 'Urine (URINE)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered 'Negative (NEGATIVE)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered empty.	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:38
User entered empty.	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered empty.	System	02 Oct 2020 19:51:02

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:12:37



**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:12:37

US3762131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:12:37

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:12:37

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered '9:54'	(b) (4), (b) (6)	29 Sep 2020 14:12:37

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '29 Sep 2020 9:54'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Sep 2020 14:12:37

US3762131

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:37:24
User entered 'ONCE'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:42:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:40

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:49
User entered '29 Sep 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:40

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:49
User entered '09:27'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:51:40

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '29 Sep 2020 09:27'	System	02 Oct 2020 19:51:40

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:56
User entered '29 Sep 2020'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:56
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:52:12



**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:56
User entered '09:31'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '29 Sep 2020 09:31'	System	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	James Lovette (b) (4)	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:56
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:36:56
User entered empty.	James Lovette (b) (4) (b) (4)	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered empty.	System	02 Oct 2020 19:52:12

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:37:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:50

**US3762131**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	29 Sep 2020 14:11:50



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1369effe-9020-405d-803c-01e183931dd8'	System	29 Sep 2020 14:33:23
User entered 'Yes (Y)'	System	29 Sep 2020 14:33:23

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1369effe-9020-405d-803c-01e183931dd8'	System	29 Sep 2020 14:33:23
User entered '98.2'	System	29 Sep 2020 14:33:23

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:19', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1369effe-9020-405d-803c-01e183931dd8'	System	29 Sep 2020 14:33:23
User entered 'No (N)'	System	29 Sep 2020 14:33:23

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:22', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1369effe-9020-405d-803c-01e183931dd8'	System	29 Sep 2020 14:33:23
User entered '29 Sep 2020 10:33'	System	29 Sep 2020 14:33:23

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 10:14'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 12:44'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T17:08:42', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '56a752b6-0bec-45d9-9f2d-4693cc400345'	System	29 Sep 2020 21:09:05
User entered 'Yes (Y)'	System	29 Sep 2020 21:09:05

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T17:08:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '56a752b6-0bec-45d9-9f2d-4693cc400345' User entered '99.3'	System	29 Sep 2020 21:09:05

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T17:08:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '56a752b6-0bec-45d9-9f2d-4693cc400345'	System	29 Sep 2020 21:09:05
User entered 'No (N)'	System	29 Sep 2020 21:09:05

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T17:08:55', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '56a752b6-0bec-45d9-9f2d-4693cc400345'	System	29 Sep 2020 21:09:05
User entered '29 Sep 2020 17:08'	System	29 Sep 2020 21:09:05

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 13:39'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 2'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:07:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f94d9064-3480-4372-8797-991e14680727'	System	30 Sep 2020 17:08:19
User entered 'Yes (Y)'	System	30 Sep 2020 17:08:19



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:07:54', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f94d9064-3480-4372-8797-991e14680727' User entered '100.5'	System	30 Sep 2020 17:08:19
	System	30 Sep 2020 17:08:19

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:07:57', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f94d9064-3480-4372-8797-991e14680727'	System	30 Sep 2020 17:08:19
User entered 'Yes (Y)'	System	30 Sep 2020 17:08:19

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'med taken' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 08:27:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:08:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f94d9064-3480-4372-8797-991e14680727'	Samantha Wheeler (b) (4)	13 Oct 2020 13:34:11
User entered '1'	System	30 Sep 2020 17:08:19

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:42:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:08:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f94d9064-3480-4372-8797-991e14680727' User entered '0'	System	30 Sep 2020 17:08:19
	System	30 Sep 2020 17:08:19

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:08:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f94d9064-3480-4372-8797-991e14680727'	System	30 Sep 2020 17:08:19
User entered '30 Sep 2020 13:08'	System	30 Sep 2020 17:08:19

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 3'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7c8640ce-455f-4702-bf77-51ccb510ebcc'	System	01 Oct 2020 23:26:46
User entered 'Yes (Y)'	System	01 Oct 2020 23:26:46

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:29', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7c8640ce-455f-4702-bf77-51ccb510ebcc' User entered '97.4'	System	01 Oct 2020 23:26:46
	System	01 Oct 2020 23:26:46

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7c8640ce-455f-4702-bf77-51ccb510ebcc'	System	01 Oct 2020 23:26:46
User entered 'Yes (Y)'	System	01 Oct 2020 23:26:46

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'med taken' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 08:27:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:39', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7c8640ce-455f-4702-bf77-51ccb510ebcc'	Samantha Wheeler (b) (4)	13 Oct 2020 13:34:19
User entered '1'	System	01 Oct 2020 23:26:46
	System	01 Oct 2020 23:26:46
	System	01 Oct 2020 23:26:46

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:42:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:39', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7c8640ce-455f-4702-bf77-51ccb510ebcc'	System	01 Oct 2020 23:26:46
User entered '0'	System	01 Oct 2020 23:26:46

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:43', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7c8640ce-455f-4702-bf77-51ccb510ebcc'	System	01 Oct 2020 23:26:46
User entered '01 Oct 2020 19:26'	System	01 Oct 2020 23:26:46

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 4'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9598a3f7-c294-48d3-abd2-322f1ee7d6e9'	System	02 Oct 2020 19:10:41
User entered 'Yes (Y)'	System	02 Oct 2020 19:10:41

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:30', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9598a3f7-c294-48d3-abd2-322f1ee7d6e9' User entered '98.2'	System	02 Oct 2020 19:10:41
	System	02 Oct 2020 19:10:41

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:33', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9598a3f7-c294-48d3-abd2-322f1ee7d6e9'	System	02 Oct 2020 19:10:41
User entered 'Yes (Y)'	System	02 Oct 2020 19:10:41

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'med taken' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 08:27:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:36', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9598a3f7-c294-48d3-abd2-322f1ee7d6e9'	Samantha Wheeler (b) (4)	13 Oct 2020 13:34:27
User entered '1'	System	02 Oct 2020 19:10:41
	System	02 Oct 2020 19:10:41
	System	02 Oct 2020 19:10:41

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:36', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9598a3f7-c294-48d3-abd2-322f1ee7d6e9'	System	02 Oct 2020 19:10:41
User entered '0'	System	02 Oct 2020 19:10:41

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9598a3f7-c294-48d3-abd2-322f1ee7d6e9'	System	02 Oct 2020 19:10:41
User entered '02 Oct 2020 15:10'	System	02 Oct 2020 19:10:41

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 5'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:46:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3c1fe34-92d7-4310-8b3c-3c2eee68f7e1'	System	03 Oct 2020 23:46:59
User entered 'Yes (Y)'	System	03 Oct 2020 23:46:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:46:46', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3c1fe34-92d7-4310-8b3c-3c2eee68f7e1' User entered '97.7'	System	03 Oct 2020 23:46:59
	System	03 Oct 2020 23:46:59

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:46:49', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3c1fe34-92d7-4310-8b3c-3c2eee68f7e1'	System	03 Oct 2020 23:46:59
User entered 'No (N)'	System	03 Oct 2020 23:46:59

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:46:53', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b3c1fe34-92d7-4310-8b3c-3c2eee68f7e1'	System	03 Oct 2020 23:46:59
User entered '03 Oct 2020 19:46'	System	03 Oct 2020 23:46:59

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 6'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T19:57:32', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ccb0d543-ac41-40ca-9f79-0bdf3c914725'	System	04 Oct 2020 23:57:45
User entered 'Yes (Y)'	System	04 Oct 2020 23:57:45

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T19:57:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ccb0d543-ac41-40ca-9f79-0bdf3c914725' User entered '97.7'	System	04 Oct 2020 23:57:45
	System	04 Oct 2020 23:57:45

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T19:57:40', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ccb0d543-ac41-40ca-9f79-0bdf3c914725'	System	04 Oct 2020 23:57:45
User entered 'No (N)'	System	04 Oct 2020 23:57:45

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T19:57:43', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ccb0d543-ac41-40ca-9f79-0bdf3c914725' User entered '04 Oct 2020 19:57'	System	04 Oct 2020 23:57:45
	System	04 Oct 2020 23:57:45

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 7'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T20:50:28', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '29f57274-1571-4063-8229-6876138dcbbc'	System	06 Oct 2020 00:50:39
User entered 'Yes (Y)'	System	06 Oct 2020 00:50:39

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T20:50:33', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '29f57274-1571-4063-8229-6876138dcbbc'	System	06 Oct 2020 00:50:39
User entered '98.6'	System	06 Oct 2020 00:50:39

US3762131

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T20:50:36', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '29f57274-1571-4063-8229-6876138dcbbc'	System	06 Oct 2020 00:50:39
User entered 'No (N)'	System	06 Oct 2020 00:50:39

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T20:50:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '29f57274-1571-4063-8229-6876138dcbbc'	System	06 Oct 2020 00:50:39
User entered '05 Oct 2020 20:50'	System	06 Oct 2020 00:50:39

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:35', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '820eb9cc-65ac-4b96-8edd-8b62102c31d4'	System	29 Sep 2020 14:33:54
User entered 'None (1)'	System	29 Sep 2020 14:33:54



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:46', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '820eb9cc-65ac-4b96-8edd-8b62102c31d4'	System	29 Sep 2020 14:33:54
User entered 'No (N)'	System	29 Sep 2020 14:33:54

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:48', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '820eb9cc-65ac-4b96-8edd-8b62102c31d4'	System	29 Sep 2020 14:33:54
User entered 'No (N)'	System	29 Sep 2020 14:33:54

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:53', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '820eb9cc-65ac-4b96-8edd-8b62102c31d4'	System	29 Sep 2020 14:33:54
User entered 'None (1)'	System	29 Sep 2020 14:33:54

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:33:56', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '820eb9cc-65ac-4b96-8edd-8b62102c31d4'	System	29 Sep 2020 14:33:54
User entered '29 Sep 2020 10:33'	System	29 Sep 2020 14:33:54

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 10:14'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 12:44'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T18:25:12', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'a8aba835-b014-4ec7-a696-336ad43dd000'	System	29 Sep 2020 22:26:26
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 22:26:26



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T18:25:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'a8aba835-b014-4ec7-a696-336ad43dd000'	System	29 Sep 2020 22:26:26
User entered 'No (N)'	System	29 Sep 2020 22:26:26

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T18:25:20', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'a8aba835-b014-4ec7-a696-336ad43dd000'	System	29 Sep 2020 22:26:26
User entered 'Yes (Y)'	System	29 Sep 2020 22:26:26

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T18:26:14', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'a8aba835-b014-4ec7-a696-336ad43dd000'	System	29 Sep 2020 22:26:26
User entered '20'	System	29 Sep 2020 22:26:26

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T18:26:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'a8aba835-b014-4ec7-a696-336ad43dd000'	System	29 Sep 2020 22:26:26
User entered 'None (1)'	System	29 Sep 2020 22:26:26

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T18:26:23', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'a8aba835-b014-4ec7-a696-336ad43dd000'	System	29 Sep 2020 22:26:26
User entered '29 Sep 2020 18:26'	System	29 Sep 2020 22:26:26

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 13:39'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 2'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:05:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4962f394-c82b-4005-9efe-220026710eb1'	System	30 Sep 2020 17:05:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	30 Sep 2020 17:05:40

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:05:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4962f394-c82b-4005-9efe-220026710eb1'	System	30 Sep 2020 17:05:40
User entered 'No (N)'	System	30 Sep 2020 17:05:40

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:05:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4962f394-c82b-4005-9efe-220026710eb1'	System	30 Sep 2020 17:05:40
User entered 'Yes (Y)'	System	30 Sep 2020 17:05:40

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:05:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4962f394-c82b-4005-9efe-220026710eb1'	System	30 Sep 2020 17:05:40
User entered '30'	System	30 Sep 2020 17:05:40

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:05:30', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4962f394-c82b-4005-9efe-220026710eb1'	System	30 Sep 2020 17:05:40
User entered 'None (1)'	System	30 Sep 2020 17:05:40

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:05:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4962f394-c82b-4005-9efe-220026710eb1'	System	30 Sep 2020 17:05:40
User entered '30 Sep 2020 13:05'	System	30 Sep 2020 17:05:40

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 3'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:49', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8b94dbbe-458c-41c5-a337-2a571148031a'	System	01 Oct 2020 23:27:10
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 23:27:10

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:52', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8b94dbbe-458c-41c5-a337-2a571148031a'	System	01 Oct 2020 23:27:10
User entered 'No (N)'	System	01 Oct 2020 23:27:10

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:26:58', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8b94dbbe-458c-41c5-a337-2a571148031a'	System	01 Oct 2020 23:27:10
User entered 'No (N)'	System	01 Oct 2020 23:27:10

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8b94dbbe-458c-41c5-a337-2a571148031a'	System	01 Oct 2020 23:27:10
User entered 'None (1)'	System	01 Oct 2020 23:27:10

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8b94dbbe-458c-41c5-a337-2a571148031a'	System	01 Oct 2020 23:27:10
User entered '01 Oct 2020 19:27'	System	01 Oct 2020 23:27:10

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 4'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9e0f9494-968c-4951-83a3-469f4c8160c9'	System	02 Oct 2020 19:10:18
User entered 'None (1)'	System	02 Oct 2020 19:10:18

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9e0f9494-968c-4951-83a3-469f4c8160c9'	System	02 Oct 2020 19:10:18
User entered 'No (N)'	System	02 Oct 2020 19:10:18

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:10', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9e0f9494-968c-4951-83a3-469f4c8160c9'	System	02 Oct 2020 19:10:18
User entered 'No (N)'	System	02 Oct 2020 19:10:18

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9e0f9494-968c-4951-83a3-469f4c8160c9'	System	02 Oct 2020 19:10:18
User entered 'None (1)'	System	02 Oct 2020 19:10:18

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:15', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9e0f9494-968c-4951-83a3-469f4c8160c9'	System	02 Oct 2020 19:10:18
User entered '02 Oct 2020 15:10'	System	02 Oct 2020 19:10:18

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 5'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:46:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '42ab5987-032f-4c0d-840a-486b12c27214'	System	03 Oct 2020 23:47:16
User entered 'None (1)'	System	03 Oct 2020 23:47:16

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '42ab5987-032f-4c0d-840a-486b12c27214'	System	03 Oct 2020 23:47:16
User entered 'No (N)'	System	03 Oct 2020 23:47:16

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '42ab5987-032f-4c0d-840a-486b12c27214'	System	03 Oct 2020 23:47:16
User entered 'No (N)'	System	03 Oct 2020 23:47:16

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:12', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '42ab5987-032f-4c0d-840a-486b12c27214'	System	03 Oct 2020 23:47:16
User entered 'None (1)'	System	03 Oct 2020 23:47:16

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:15', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '42ab5987-032f-4c0d-840a-486b12c27214'	System	03 Oct 2020 23:47:16
User entered '03 Oct 2020 19:47'	System	03 Oct 2020 23:47:16

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 6'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:19', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1a8a58fc-259b-4428-8b8b-720d6c5260c1'	System	04 Oct 2020 22:04:34
User entered 'None (1)'	System	04 Oct 2020 22:04:34

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1a8a58fc-259b-4428-8b8b-720d6c5260c1'	System	04 Oct 2020 22:04:34
User entered 'No (N)'	System	04 Oct 2020 22:04:34

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1a8a58fc-259b-4428-8b8b-720d6c5260c1'	System	04 Oct 2020 22:04:34
User entered 'No (N)'	System	04 Oct 2020 22:04:34

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1a8a58fc-259b-4428-8b8b-720d6c5260c1'	System	04 Oct 2020 22:04:34
User entered 'None (1)'	System	04 Oct 2020 22:04:34

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:32', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '1a8a58fc-259b-4428-8b8b-720d6c5260c1'	System	04 Oct 2020 22:04:34
User entered '04 Oct 2020 18:04'	System	04 Oct 2020 22:04:34

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 7'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:25', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c8ede12d-1ca4-4e9a-b57b-485a9460a1ec'	System	05 Oct 2020 18:20:39
User entered 'None (1)'	System	05 Oct 2020 18:20:39

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c8ede12d-1ca4-4e9a-b57b-485a9460a1ec'	System	05 Oct 2020 18:20:39
User entered 'No (N)'	System	05 Oct 2020 18:20:39

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:29', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c8ede12d-1ca4-4e9a-b57b-485a9460a1ec'	System	05 Oct 2020 18:20:39
User entered 'No (N)'	System	05 Oct 2020 18:20:39

US3762131

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:32', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c8ede12d-1ca4-4e9a-b57b-485a9460a1ec'	System	05 Oct 2020 18:20:39
User entered 'None (1)'	System	05 Oct 2020 18:20:39

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c8ede12d-1ca4-4e9a-b57b-485a9460a1ec'	System	05 Oct 2020 18:20:39
User entered '05 Oct 2020 14:20'	System	05 Oct 2020 18:20:39

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'None (0)'	System	29 Sep 2020 14:34:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'None (0)'	System	29 Sep 2020 14:34:37

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'None (0)'	System	29 Sep 2020 14:34:37

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:14', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'None (0)'	System	29 Sep 2020 14:34:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'None (0)'	System	29 Sep 2020 14:34:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:30', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'None (0)'	System	29 Sep 2020 14:34:37

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered 'No (N)'	System	29 Sep 2020 14:34:37



**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T10:34:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ee49c0c9-761d-455a-832c-23427df5b63c'	System	29 Sep 2020 14:34:37
User entered '29 Sep 2020 10:34'	System	29 Sep 2020 14:34:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 10:14'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 12:44'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:04:57', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'None (0)'	System	29 Sep 2020 20:05:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'None (0)'	System	29 Sep 2020 20:05:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'None (0)'	System	29 Sep 2020 20:05:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:07', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'None (0)'	System	29 Sep 2020 20:05:22



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:10', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'None (0)'	System	29 Sep 2020 20:05:22

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'None (0)'	System	29 Sep 2020 20:05:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered 'No (N)'	System	29 Sep 2020 20:05:22

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-29T16:05:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd64a73c5-7d11-40df-b34a-61b9820cac96'	System	29 Sep 2020 20:05:22
User entered '29 Sep 2020 16:05'	System	29 Sep 2020 20:05:22

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '29 Sep 2020 13:39'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 2'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:03:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:04:31



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'None (0)'	System	30 Sep 2020 17:04:31

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:07', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'None (0)'	System	30 Sep 2020 17:04:31

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'None (0)'	System	30 Sep 2020 17:04:31

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:14', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'None (0)'	System	30 Sep 2020 17:04:31

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'None (0)'	System	30 Sep 2020 17:04:31

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered 'No (N)'	System	30 Sep 2020 17:04:31

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-09-30T13:04:28', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7680dde7-c613-4683-9237-bcce720085a2'	System	30 Sep 2020 17:04:31
User entered '30 Sep 2020 13:04'	System	30 Sep 2020 17:04:31

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 3'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:09', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'None (0)'	System	01 Oct 2020 23:27:38

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'None (0)'	System	01 Oct 2020 23:27:38

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:15', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'None (0)'	System	01 Oct 2020 23:27:38

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'None (0)'	System	01 Oct 2020 23:27:38

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:20', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'None (0)'	System	01 Oct 2020 23:27:38

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'None (0)'	System	01 Oct 2020 23:27:38



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:33', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered 'No (N)'	System	01 Oct 2020 23:27:38

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-01T19:27:36', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7f53e0f4-cd4c-4788-8a1d-b48d0dc6c502'	System	01 Oct 2020 23:27:38
User entered '01 Oct 2020 19:27'	System	01 Oct 2020 23:27:38

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 4'	System	29 Sep 2020 14:12:37

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:39', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'None (0)'	System	02 Oct 2020 19:10:06

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:42', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'None (0)'	System	02 Oct 2020 19:10:06

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:44', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'None (0)'	System	02 Oct 2020 19:10:06



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'None (0)'	System	02 Oct 2020 19:10:06

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'None (0)'	System	02 Oct 2020 19:10:06

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:52', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'None (0)'	System	02 Oct 2020 19:10:06

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:09:57', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered 'No (N)'	System	02 Oct 2020 19:10:06

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-02T15:10:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37fe85dd-f7ba-4caf-9eb1-dc7bd8273eb1'	System	02 Oct 2020 19:10:06
User entered '02 Oct 2020 15:10'	System	02 Oct 2020 19:10:06

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 5'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'None (0)'	System	03 Oct 2020 23:47:48

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:27', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'None (0)'	System	03 Oct 2020 23:47:48

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:29', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'None (0)'	System	03 Oct 2020 23:47:48

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:33', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'None (0)'	System	03 Oct 2020 23:47:48

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:35', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'None (0)'	System	03 Oct 2020 23:47:48

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'None (0)'	System	03 Oct 2020 23:47:48

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:40', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered 'No (N)'	System	03 Oct 2020 23:47:48

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-03T19:47:46', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3c2080df-8053-435d-94ce-1f700c451d5a'	System	03 Oct 2020 23:47:48
User entered '03 Oct 2020 19:47'	System	03 Oct 2020 23:47:48



**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 6'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:03:56', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'None (0)'	System	04 Oct 2020 22:04:14

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:03:59', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'None (0)'	System	04 Oct 2020 22:04:14

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'None (0)'	System	04 Oct 2020 22:04:14

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'None (0)'	System	04 Oct 2020 22:04:14

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:05', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'None (0)'	System	04 Oct 2020 22:04:14



**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:07', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'None (0)'	System	04 Oct 2020 22:04:14

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:09', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered 'No (N)'	System	04 Oct 2020 22:04:14

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-04T18:04:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '790ea372-1ce6-4cda-bef8-8f5c1f4bf27e'	System	04 Oct 2020 22:04:14
User entered '04 Oct 2020 18:04'	System	04 Oct 2020 22:04:14

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	29 Sep 2020 14:12:37
User entered 'Day 7'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:02', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'None (0)'	System	05 Oct 2020 18:20:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'None (0)'	System	05 Oct 2020 18:20:22



US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:06', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'None (0)'	System	05 Oct 2020 18:20:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'None (0)'	System	05 Oct 2020 18:20:22

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:10', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'None (0)'	System	05 Oct 2020 18:20:22

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:12', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'None (0)'	System	05 Oct 2020 18:20:22

US3762131

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:42:38

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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:15', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered 'No (N)'	System	05 Oct 2020 18:20:22

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-10-05T14:20:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '79232dce-5d99-4e5b-9cbf-3abdacf0ab75'	System	05 Oct 2020 18:20:22
User entered '05 Oct 2020 14:20'	System	05 Oct 2020 18:20:22

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:12:37

**US3762131**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:42:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:12:37



**US3762131**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:01:46
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:30:54

**US3762131**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:01:46
User entered '06 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:30:54

**US3762131**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:01:46
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:30:54

**US3762131**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:01:46
User entered empty.	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:30:54

**US3762131**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:01:50
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:30:59

**US3762131**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	13 Oct 2020 19:30:59

**US3762131**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:11
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:31:13

**US3762131**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:11
User entered '13 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:31:13



**US3762131**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:11
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:31:13

**US3762131**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:11
User entered empty.	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:31:13

**US3762131**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:15
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	13 Oct 2020 19:31:25

**US3762131**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	13 Oct 2020 19:31:25

**US3762131**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:33
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	20 Oct 2020 15:58:12

**US3762131**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:33
User entered '20 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	20 Oct 2020 15:58:12

**US3762131**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:33
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	20 Oct 2020 15:58:12

**US3762131**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:33
User entered empty.	Kaitlyn Van Leuvan (b) (4)	20 Oct 2020 15:58:12



**US3762131**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:37
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	20 Oct 2020 15:58:16

**US3762131**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	20 Oct 2020 15:58:16

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:51
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:18:50

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:51
User entered '27 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:18:50

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:02:51
User entered 'Clinic (Clinic)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:18:50

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'VISIT3'	System	27 Oct 2020 16:18:50

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '27 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32



**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '09:12'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '27 Oct 2020 09:12'	System	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '98.4' F	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered 'Oral (Oral)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered empty.	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '75'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'bpm'	System	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '14'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32



**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'breaths/min'	System	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '117'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:00
User entered '74'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'mmHg'	System	27 Oct 2020 16:19:32

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:09
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:38



**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:09
User entered empty.	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:19:38

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:13
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:20:03

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:13
User entered '27 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:20:03

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:13
User entered '09:19'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:20:03

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered '27 Oct 2020 09:19'	System	27 Oct 2020 16:20:03

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:00:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:17
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	27 Oct 2020 16:20:08

**US3762131**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	27 Oct 2020 16:20:08

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 64'	System	01 Sep 2020 15:10:07



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-03T09:58:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '712e69ad-75fa-4fec-b9a0-418bd5fdd7e4'	System	03 Nov 2020 14:59:06
User entered 'No (N)'	System	03 Nov 2020 14:59:06

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

Have you been exposed to someone with 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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-03T09:59:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '712e69ad-75fa-4fec-b9a0-418bd5fdd7e4'	System	03 Nov 2020 14:59:06
User entered 'No (N)'	System	03 Nov 2020 14:59:06

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-03T09:59:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '712e69ad-75fa-4fec-b9a0-418bd5fdd7e4'	System	03 Nov 2020 14:59:06
User entered '03 Nov 2020 09:59:04'	System	03 Nov 2020 14:59:06

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 71'	System	01 Sep 2020 15:10:07

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

[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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-11T04:49:07', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bf6ef2-c0f8-495a-b23b-65680a93fee7'	System	11 Nov 2020 09:49:26
User entered 'No (N)'	System	11 Nov 2020 09:49:26

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

Have you been exposed to someone with 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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-11T04:49:17', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bf6ef2-c0f8-495a-b23b-65680a93fee7'	System	11 Nov 2020 09:49:26
User entered 'No (N)'	System	11 Nov 2020 09:49:26



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-11T04:49:23', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f3bf6ef2-c0f8-495a-b23b-65680a93fee7'	System	11 Nov 2020 09:49:26
User entered '11 Nov 2020 04:49:23'	System	11 Nov 2020 09:49:26

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered 'Day 78'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-17T08:33:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3d3d413a-83f9-4bec-9c20-1cf0572e08a4'	System	17 Nov 2020 13:34:05
User entered 'No (N)'	System	17 Nov 2020 13:34:05

US3762131

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:38

Have you been exposed to someone with 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 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-17T08:33:55', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3d3d413a-83f9-4bec-9c20-1cf0572e08a4'	System	17 Nov 2020 13:34:05
User entered 'No (N)'	System	17 Nov 2020 13:34:05

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-17T08:34:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '3d3d413a-83f9-4bec-9c20-1cf0572e08a4'	System	17 Nov 2020 13:34:05
User entered '17 Nov 2020 08:34:00'	System	17 Nov 2020 13:34:05

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 15:10:07



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:11:22
Data entry locked.	System	01 Sep 2020 15:10:07
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 15:10:07

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2020-11-26T19:35:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ec89183c-ed9a-4159-a65b-9fa5a199c525'	System	27 Nov 2020 00:35:14
User entered 'No (N)'	System	27 Nov 2020 00:35:14

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2020-11-26T19:35:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ec89183c-ed9a-4159-a65b-9fa5a199c525'	System	27 Nov 2020 00:35:14
User entered 'No (N)'	System	27 Nov 2020 00:35:14

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-11-26T19:35:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ec89183c-ed9a-4159-a65b-9fa5a199c525'	System	27 Nov 2020 00:35:14
User entered '26 Nov 2020 19:35:11'	System	27 Nov 2020 00:35:14



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2020-12-03T09:34:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '07106efb-0a61-4537-bbb0-fce1db67b8c3'	System	03 Dec 2020 14:34:20
User entered 'No (N)'	System	03 Dec 2020 14:34:20

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2020-12-03T09:34:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '07106efb-0a61-4537-bbb0-fce1db67b8c3'	System	03 Dec 2020 14:34:20
User entered 'No (N)'	System	03 Dec 2020 14:34:20

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-12-03T09:34:16', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '07106efb-0a61-4537-bbb0-fce1db67b8c3'	System	03 Dec 2020 14:34:20
User entered '03 Dec 2020 09:34:16'	System	03 Dec 2020 14:34:20

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2020-12-10T09:33:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6b9be551-2a28-4f2f-aac8-15c08beabcfe'	System	10 Dec 2020 14:33:57
User entered 'No (N)'	System	10 Dec 2020 14:33:57

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2020-12-10T09:33:52', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6b9be551-2a28-4f2f-aac8-15c08beabcfe'	System	10 Dec 2020 14:33:57
User entered 'No (N)'	System	10 Dec 2020 14:33:57

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-12-10T09:33:55', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '6b9be551-2a28-4f2f-aac8-15c08beabcfe'	System	10 Dec 2020 14:33:57
User entered '10 Dec 2020 09:33:55'	System	10 Dec 2020 14:33:57

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2020-12-17T07:12:28', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4d05a62e-ec90-4cf3-a48a-13863fe5d52f'	System	17 Dec 2020 12:12:43
User entered 'No (N)'	System	17 Dec 2020 12:12:43



**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2020-12-17T07:12:34', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4d05a62e-ec90-4cf3-a48a-13863fe5d52f'	System	17 Dec 2020 12:12:43
User entered 'No (N)'	System	17 Dec 2020 12:12:43

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-12-17T07:12:36', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '4d05a62e-ec90-4cf3-a48a-13863fe5d52f'	System	17 Dec 2020 12:12:43
User entered '17 Dec 2020 07:12:36'	System	17 Dec 2020 12:12:43

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:34:17

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2020-12-24T14:04:09', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'fa7afc62-d3b9-4d0b-99c3-fdfcefb6e402'	System	24 Dec 2020 19:04:25
User entered 'No (N)'	System	24 Dec 2020 19:04:25

**US3762131**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2020-12-24T14:04:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'fa7afc62-d3b9-4d0b-99c3-fdfcefb6e402'	System	24 Dec 2020 19:04:25
User entered 'No (N)'	System	24 Dec 2020 19:04:25

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2020-12-24T14:04:21', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'fa7afc62-d3b9-4d0b-99c3-fdfcefb6e402'	System	24 Dec 2020 19:04:25
User entered '24 Dec 2020 14:04:21'	System	24 Dec 2020 19:04:25



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-01-14T14:13:58', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66d8375-b986-4de1-96ee-cbbd58b3165f'	System	14 Jan 2021 19:14:07
User entered 'No (N)'	System	14 Jan 2021 19:14:07

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-01-14T14:14:01', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66d8375-b986-4de1-96ee-cbbd58b3165f'	System	14 Jan 2021 19:14:07
User entered 'No (N)'	System	14 Jan 2021 19:14:07

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-01-14T14:14:04', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f66d8375-b986-4de1-96ee-cbbd58b3165f' User entered '14 Jan 2021 14:14:04'	System	14 Jan 2021 19:14:07

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-01-22T13:05:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e008b8f0-fe08-4985-bd62-36425c58cbca'	System	22 Jan 2021 18:05:48
User entered 'No (N)'	System	22 Jan 2021 18:05:48



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-01-22T13:05:42', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e008b8f0-fe08-4985-bd62-36425c58cbca'	System	22 Jan 2021 18:05:48
User entered 'No (N)'	System	22 Jan 2021 18:05:48

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-01-22T13:05:45', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'e008b8f0-fe08-4985-bd62-36425c58cbca'	System	22 Jan 2021 18:05:48
User entered '22 Jan 2021 13:05:45'	System	22 Jan 2021 18:05:48

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-01-28T08:34:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '731f3f68-a09e-4b6f-ad51-004bc4bd7e6f'	System	28 Jan 2021 13:34:42
User entered 'No (N)'	System	28 Jan 2021 13:34:42

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-01-28T08:34:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '731f3f68-a09e-4b6f-ad51-004bc4bd7e6f'	System	28 Jan 2021 13:34:42
User entered 'No (N)'	System	28 Jan 2021 13:34:42

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-01-28T08:34:38', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '731f3f68-a09e-4b6f-ad51-004bc4bd7e6f' User entered '28 Jan 2021 08:34:38'	System	28 Jan 2021 13:34:42



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-02-04T08:41:03', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '340231e0-d3f3-4b89-aa99-e30fb4d52dd2'	System	04 Feb 2021 13:41:17
User entered 'No (N)'	System	04 Feb 2021 13:41:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-02-04T08:41:11', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '340231e0-d3f3-4b89-aa99-e30fb4d52dd2'	System	04 Feb 2021 13:41:17
User entered 'No (N)'	System	04 Feb 2021 13:41:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-02-04T08:41:13', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '340231e0-d3f3-4b89-aa99-e30fb4d52dd2'	System	04 Feb 2021 13:41:17
User entered '04 Feb 2021 08:41:13'	System	04 Feb 2021 13:41:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-02-11T10:09:37', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd3ed6690-ebd1-401d-b55a-f248b1058771'	System	11 Feb 2021 15:09:54
User entered 'No (N)'	System	11 Feb 2021 15:09:54

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-02-11T10:09:47', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd3ed6690-ebd1-401d-b55a-f248b1058771'	System	11 Feb 2021 15:09:54
User entered 'No (N)'	System	11 Feb 2021 15:09:54

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-02-11T10:09:50', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'd3ed6690-ebd1-401d-b55a-f248b1058771'	System	11 Feb 2021 15:09:54
User entered '11 Feb 2021 10:09:50'	System	11 Feb 2021 15:09:54

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-02-18T09:04:08', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '65ec29b6-1e5e-46e4-b0de-d8752a4a7584'	System	18 Feb 2021 14:04:47
User entered 'Yes (Y)'	System	18 Feb 2021 14:04:47



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-02-18T09:04:12', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '65ec29b6-1e5e-46e4-b0de-d8752a4a7584'	System	18 Feb 2021 14:04:47
User entered 'No (N)'	System	18 Feb 2021 14:04:47

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-02-18T09:04:18', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '65ec29b6-1e5e-46e4-b0de-d8752a4a7584'	System	18 Feb 2021 14:04:47
User entered 'No (N)'	System	18 Feb 2021 14:04:47

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-02-18T09:04:24', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '65ec29b6-1e5e-46e4-b0de-d8752a4a7584'	System	18 Feb 2021 14:04:47
User entered 'No (N)'	System	18 Feb 2021 14:04:47

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-02-18T09:04:43', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '65ec29b6-1e5e-46e4-b0de-d8752a4a7584'	System	18 Feb 2021 14:04:47
User entered '18 Feb 2021 09:04:43'	System	18 Feb 2021 14:04:47

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-02-25T09:51:00-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37d5a49d-f572-4b4e-80cd-796d4afe8705'	System	25 Feb 2021 21:59:30
User entered 'No (N)'	System	25 Feb 2021 21:59:30



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-02-25T09:51:03-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37d5a49d-f572-4b4e-80cd-796d4afe8705'	System	25 Feb 2021 21:59:30
User entered 'No (N)'	System	25 Feb 2021 21:59:30

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-02-25T09:51:05-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '37d5a49d-f572-4b4e-80cd-796d4afe8705'	System	25 Feb 2021 21:59:30
User entered '25 Feb 2021 09:51:05'	System	25 Feb 2021 21:59:30

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-03-06T14:34:57-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c4b20dc8-de42-4648-984d-5280f523215d'	System	06 Mar 2021 19:35:09
User entered 'No (N)'	System	06 Mar 2021 19:35:09

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-03-06T14:35:00-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c4b20dc8-de42-4648-984d-5280f523215d'	System	06 Mar 2021 19:35:09
User entered 'No (N)'	System	06 Mar 2021 19:35:09

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-03-06T14:35:02-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c4b20dc8-de42-4648-984d-5280f523215d' User entered '06 Mar 2021 14:35:02'	System	06 Mar 2021 19:35:09



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-03-13T12:39:37-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '39d1770b-6f23-4163-a29b-a3394738c9de' User entered 'No (N)'	System	13 Mar 2021 17:39:46
	System	13 Mar 2021 17:39:46

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-03-13T12:39:39-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '39d1770b-6f23-4163-a29b-a3394738c9de'	System	13 Mar 2021 17:39:46
User entered 'No (N)'	System	13 Mar 2021 17:39:46

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-03-13T12:39:41-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '39d1770b-6f23-4163-a29b-a3394738c9de' User entered '13 Mar 2021 12:39:41'	System	13 Mar 2021 17:39:46
	System	13 Mar 2021 17:39:46

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-03-18T07:38:30-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9be99154-214e-4d40-b8b7-10fd176c2f51'	System	18 Mar 2021 11:38:41
User entered 'No (N)'	System	18 Mar 2021 11:38:41

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-03-18T07:38:34-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9be99154-214e-4d40-b8b7-10fd176c2f51'	System	18 Mar 2021 11:38:41
User entered 'No (N)'	System	18 Mar 2021 11:38:41

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-03-18T07:38:37-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '9be99154-214e-4d40-b8b7-10fd176c2f51' User entered '18 Mar 2021 07:38:37'	System	18 Mar 2021 11:38:41
	System	18 Mar 2021 11:38:41

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-03-25T06:15:58-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c9be7463-fe5f-4664-95e2-6aad1bc7d626'	System	25 Mar 2021 10:16:11
User entered 'No (N)'	System	25 Mar 2021 10:16:11



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-03-25T06:15:53-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c9be7463-fe5f-4664-95e2-6aad1bc7d626'	System	25 Mar 2021 10:16:11
User entered 'No (N)'	System	25 Mar 2021 10:16:11

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-03-25T06:16:06-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'c9be7463-fe5f-4664-95e2-6aad1bc7d626'	System	25 Mar 2021 10:16:11
User entered '25 Mar 2021 06:16:06'	System	25 Mar 2021 10:16:11

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-04-01T08:32:09-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0bc5974e-4743-485b-a25e-8b1bd58585bc'	System	01 Apr 2021 12:32:19
User entered 'No (N)'	System	01 Apr 2021 12:32:19

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-04-01T08:32:13-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0bc5974e-4743-485b-a25e-8b1bd58585bc'	System	01 Apr 2021 12:32:19
User entered 'No (N)'	System	01 Apr 2021 12:32:19

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-04-01T08:32:15-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '0bc5974e-4743-485b-a25e-8b1bd58585bc'	System	01 Apr 2021 12:32:19
User entered '01 Apr 2021 08:32:15'	System	01 Apr 2021 12:32:19



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-04-08T07:31:46-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ac871797-a5c6-4368-9ac0-30003af9b898'	System	08 Apr 2021 11:31:56
User entered 'No (N)'	System	08 Apr 2021 11:31:56

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-04-08T07:31:50-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ac871797-a5c6-4368-9ac0-30003af9b898'	System	08 Apr 2021 11:31:56
User entered 'No (N)'	System	08 Apr 2021 11:31:56

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-04-08T07:31:52-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'ac871797-a5c6-4368-9ac0-30003af9b898'	System	08 Apr 2021 11:31:56
User entered '08 Apr 2021 07:31:52'	System	08 Apr 2021 11:31:56

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-04-15T07:08:44-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8adbeef1-3b6c-4d51-9f0c-43252262ccfd'	System	15 Apr 2021 11:09:20
User entered 'No (N)'	System	15 Apr 2021 11:09:20

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-04-15T07:08:48-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8adbeef1-3b6c-4d51-9f0c-43252262ccfd'	System	15 Apr 2021 11:09:20
User entered 'No (N)'	System	15 Apr 2021 11:09:20

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-04-15T07:09:14-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '8adbeef1-3b6c-4d51-9f0c-43252262ccfd'	System	15 Apr 2021 11:09:20
User entered '15 Apr 2021 07:09:14'	System	15 Apr 2021 11:09:20

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-04-22T01:54:23-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f69a9c34-5514-4531-9e93-79cc90e01a07'	System	22 Apr 2021 05:54:37
User entered 'No (N)'	System	22 Apr 2021 05:54:37



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-04-22T01:54:29-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f69a9c34-5514-4531-9e93-79cc90e01a07'	System	22 Apr 2021 05:54:37
User entered 'No (N)'	System	22 Apr 2021 05:54:37

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-04-22T01:54:32-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'f69a9c34-5514-4531-9e93-79cc90e01a07'	System	22 Apr 2021 05:54:37
User entered '22 Apr 2021 01:54:32'	System	22 Apr 2021 05:54:37

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[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 (c9f0f4a27de9270c)', Time: '2021-04-29T00:02:04-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7e7c7873-b6b4-471c-ae35-e35a8ef1d67d' User entered 'No (N)'	System	29 Apr 2021 04:03:12
	System	29 Apr 2021 04:03:12

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

Have you been exposed to someone with 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 (c9f0f4a27de9270c)', Time: '2021-04-29T00:02:07-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7e7c7873-b6b4-471c-ae35-e35a8ef1d67d' User entered 'No (N)'	System	29 Apr 2021 04:03:12

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-04-29T00:02:11-04:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: '7e7c7873-b6b4-471c-ae35-e35a8ef1d67d' User entered '29 Apr 2021 00:02:11'	System	29 Apr 2021 04:03:12
	System	29 Apr 2021 04:03:12



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:34:17



**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:34:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:34:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:34:17

**US3762131**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:42:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:34:17
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:34:17

US3762131

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:42:38**

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)	30 Apr 2021 18:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-03-06T14:35:10-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b39e799c-8ff2-457a-938c-144a69e76a72'	System	06 Mar 2021 19:35:16
User entered 'No (N)'	System	06 Mar 2021 19:35:16



**US3762131**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:35:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9f0f4a27de9270c)', Time: '2021-03-06T14:35:14-05:00', User OID: 'PatientReportedOutcome (US3762131)', ODM File OID: 'b39e799c-8ff2-457a-938c-144a69e76a72'	System	06 Mar 2021 19:35:16
User entered '06 Mar 2021 14:35:14'	System	06 Mar 2021 19:35:16

**US3762131**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:30:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 14:47:26

**US3762131**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:30:39
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 15:03:58
User entered '24 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 14:47:26

**US3762131**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:30:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Nov 2020 14:47:26

**US3762131**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:30:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:03:58
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:47:26

**US3762131**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:30:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 15:04:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 14:47:32

**US3762131**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:24:31
User entered 'I'	System	24 Nov 2020 14:47:32

**US3762131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:10:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 14:26:57



**US3762131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:10:40
User entered '29 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 14:26:57

**US3762131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:10:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 14:26:57

**US3762131**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:10:40
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:26:57

**US3762131**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:10:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 14:27:00

**US3762131**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User entered 'I'	System	29 Dec 2020 14:27:00

US3762131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:14
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:25:36
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	23 Feb 2021 11:19:37
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:27:03
' answered with 'updated' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:26:57

US3762131

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 14-Jan-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.  ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 04:42:06
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 14JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:17:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 13:23:51

**US3762131**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:59:14
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 13:23:51



**US3762131**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:59:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Jan 2021 13:23:51

**US3762131**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:59:14
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 13:23:51

**US3762131**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:01:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 13:23:57

**US3762131**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User entered 'I'	System	26 Jan 2021 13:23:57

**US3762131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:01:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 14:28:20

**US3762131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:01:34
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 14:28:20

**US3762131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:01:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 14:28:20

**US3762131**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:42:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:01:34
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 14:28:20



**US3762131**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:01:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 14:28:27

**US3762131**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:51:20
User entered 'I'	System	23 Feb 2021 14:28:27

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:06:45

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:01
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 15:06:45

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Mar 2021 15:06:45

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 15:06:45

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52



**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52



**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:08
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:42:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 15:06:52

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:14
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 15:06:57

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:42:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:14
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:06:57

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:07:12



**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:26
User entered '30 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 15:07:12

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:26
User entered '10:05'	(b) (4), (b) (6)	30 Mar 2021 15:07:12

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 10:05'	System	30 Mar 2021 15:07:12

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:46:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:07:18

**US3762131**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 15:07:18

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:14
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:28:53

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:14
User entered '14 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:28:53

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:14
User entered 'Clinic (Clinic)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:28:53



**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:42:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 18:28:53

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered '14 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[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 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 18:07:27
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:25

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Mar 2021 18:07:27
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:25

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered '14 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22



**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:33:56
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:42:38**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered empty.	System	05 Feb 2021 18:29:22

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:30
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:41

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:30
User entered '14 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:41

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:30
User entered '14:22'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:41

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '14 Jan 2021 14:22'	System	05 Feb 2021 18:29:41



**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:42:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:34
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:56

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:34
User entered '14 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:56

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:04:34
User entered '14:26'	Kaitlyn Van Leuvan (b) (4)	05 Feb 2021 18:29:56

**US3762131**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:42:38**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:37
User entered '14 Jan 2021 14:26'	System	05 Feb 2021 18:29:56

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:42:38**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:17
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:29:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:53:44
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:43:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:11:19
User closed query 'Per DM CLR: Please review this worsening AE and please note that there is no recorded baseline MH or prior AE to support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:55:33
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis NOS aggravated - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 22:27:27
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 22:27:27
	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 22:11:08
Query 'Per DM CLR: Please review this worsening AE and please note that there is no recorded baseline MH or prior AE to support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' answered with 'update' (Site from DM).	Samantha Wheeler (b) (4)	03 Nov 2020 22:10:23
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	03 Nov 2020 22:10:13
	(b) (4)	
Coding entries removed.	Samantha Wheeler (b) (4)	03 Nov 2020 22:10:13
	(b) (4)	
User entered 'DERMATITIS worsening' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	03 Nov 2020 22:10:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 15:56:15
	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please review this worsening AE and please note that there is no recorded baseline MH or prior AE to support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:43:53

US3762131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis, LLT: Dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:43:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:43:42
Data point term sent to Coder	System	21 Sep 2020 13:49:54
User entered 'dermatitis present prior to study but worsened'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '08 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 13:48:59

US3762131

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:03:42
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'OCCURS INTERMITTENTLY' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:51:52
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 02:36:42
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'Not Related (NOT RELATED)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'Not Related (NOT RELATED)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'None (NONE)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'I'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 15:56:15
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 13:48:59

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 13:48:59



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:53:14
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'USA-US130-2021-mRNA-1273-P301000006'	System	24 Mar 2021 14:45:45
User entered 'New'	(b) (4), (b) (6)	24 Mar 2021 14:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:51:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Fracture displacement, LLT: Fracture displacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:27:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:27:30
Data point term sent to Coder	System	23 Mar 2021 13:27:52
User entered 'Closed displaced pilon fracture of right tibia'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '20 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 13:27:08



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	05 Apr 2021 17:50:08
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:52:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 16:52:16
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:06:04
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'the event has an end date? Please clarify ' (Site from DM).	Samantha Wheeler (b) (4)	22 Apr 2021 17:00:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 14:30:45
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:50:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Mar 2021 17:51:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Mar 2021 17:51:42
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Mar 2021 16:52:16
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 16:52:16
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 16:52:16
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:08:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:08:13
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:02:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:02:29
User entered empty.	System	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

US3762131

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:51:41
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Mar 2021 13:27:29
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Mar 2021 13:27:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:47:50
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date included below ' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 18:24:22
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		23 Mar 2021 13:27:29
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		23 Mar 2021 13:27:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Mar 2021 13:27:29
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 13:27:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Mar 2021 13:27:08
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '20 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:50:08
DataPoint Un-verified.		
	Samantha Wheeler (b) (4)	26 Mar 2021 16:58:50
	(b) (4)	
User entered '23 Mar 2021' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	26 Mar 2021 16:58:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:50:08
DataPoint Un-verified.	Samantha Wheeler (b) (4)	26 Mar 2021 16:58:50
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	26 Mar 2021 16:58:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'All lab values have been added to the narrative provided by discharge paperwork ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:49:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:34:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:02:42
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 11:06:39
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'data present ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:48:08
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 18:32:54
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:35:14
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 20:47:24
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:50:08
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:51:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 17:51:42
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 13:27:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User closed query 'PV Query: please review if "distal fibula fracture that extended to the lateral malleolus with posterior displacement and slight valgus deformity of the fibula" requires SAE reporting ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 12:50:26
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)	07 Apr 2021 12:50:19
User closed query 'PV Query: How did subject sustain the fracture? ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 12:49:56
Query 'PV Query: please review if "distal fibula fracture that extended to the lateral malleolus with posterior displacement and slight valgus deformity of the fibula" requires SAE reporting ' answered with 'new SAE created ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:51:19
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 'con procedures, lab values, and con meds have all been updated ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:35:35
Query 'PV Query: How did subject sustain the fracture? ' answered with 'updated into narrative per patient report ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:35:18
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 13:35:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'COMMINUTED FRACTURES OF THE DISTAL TIBIA; DISTAL FIBULAR FRACTURE WHICH EXTENDS TO THE LATERAL MALLEOLUS. POSTERIOR DISPLACEMENT AND SLIGHT VALGUS DEFORMITY OF THE FIBULA" S/P "CLOSED REDUCTION RIGHT DISTAL TIBIA AND FIBULA FRACTURES WITH APPLICATION OF ANKLE SPANNING EXTERNAL FIXATOR. Patient sustained this injury from a fall down a slide. CBC DRAWN 3/21/2021 SHOWS WBC 7.3, RBC 3.77, HEMOGLOBIN 11.8, HEMATOCRIT 35.9. COVID TEST WAS NOT PERFORMED PER ELECTRONIC MEDICAL RECORD.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 13:35:06
	(b) (4), (b) (6)	05 Apr 2021 17:50:08
User opened query 'PV Query: please review if "distal fibula fracture that extended to the lateral malleolus with posterior displacement and slight valgus deformity of the fibula" requires SAE reporting ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:04:00
User opened query 'PV Query: How did subject sustain the fracture? ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:03:32
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. ' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:03:27
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)	02 Apr 2021 23:03:12
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:02:08

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:39:06
User entered 'COMMINUTED FRACTURES OF THE DISTAL TIBIA; DISTAL FIBULAR FRACTURE WHICH EXTENDS TO THE LATERAL MALLEOLUS. POSTERIOR DISPLACEMENT AND SLIGHT VALGUS DEFORMITY OF THE FIBULA" S/P "CLOSED REDUCTION RIGHT DISTAL TIBIA AND FIBULA FRACTURES WITH APPLICATION OF ANKLE SPANNING EXTERNAL FIXATOR. CBC drawn 3/21/2021 shows WBC 7.3, RBC 3.77, Hemoglobin 11.8, Hematocrit 35.9. Covid test was not performed per electronic medical record.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 18:39:06
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:51:41
User entered 'Comminuted fractures of the distal tibia; distal fibular fracture which extends to the lateral malleolus. Posterior displacement and slight valgus deformity of the fibula" s/p "closed reduction right distal tibia and fibula fractures with application of ankle spanning external fixator.'	(b) (4), (b) (6)	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 13:27:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 16:58:50

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 12:55:56
User entered	(b) (4), (b) (6)	07 Apr 2021 12:55:52
'USA-US130-2021-mRNA-1273-P301000006'		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:42:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:53:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Fibula fracture, LLT: Fibula fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 06:53:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 06:53:31
Data point term sent to Coder	System	06 Apr 2021 13:53:47
User entered 'Comminuted distal fibular fracture'	(b) (4), (b) (6)	06 Apr 2021 13:53:01



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '20 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 13:53:01

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '23 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 13:53:01



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

US3762131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:42:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:53:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		06 Apr 2021 13:53:42
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		06 Apr 2021 13:53:42
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Apr 2021 13:53:01
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '20 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 13:53:01



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '23 Mar 2021'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 13:53:42
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

US3762131

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:42:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
User closed query 'Per DM CLR: Please review and verify if this field is applicable as there is a Concomitant Procedure that matches with this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:03:38
Query 'Per DM CLR: Please review and verify if this field is applicable as there is a Concomitant Procedure that matches with this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'Procedure was only found to be done to the tibia per electronic medical record ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 20:43:54
User opened query 'Per DM CLR: Please review and verify if this field is applicable as there is a Concomitant Procedure that matches with this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 00:29:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	19 Apr 2021 17:33:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:53:00
User entered 'COMMINUTED FRACTURES OF THE DISTAL TIBIA; DISTAL FIBULAR FRACTURE WHICH EXTENDS TO THE LATERAL MALLEOLUS. POSTERIOR DISPLACEMENT AND SLIGHT VALGUS DEFORMITY OF THE FIBULA" S/P "CLOSED REDUCTION RIGHT DISTAL TIBIA AND FIBULA FRACTURES WITH APPLICATION OF ANKLE SPANNING EXTERNAL FIXATOR. PATIENT SUSTAINED THIS INJURY FROM A FALL DOWN A SLIDE. CBC DRAWN 3/21/2021 SHOWS WBC 7.3, RBC 3.77, HEMOGLOBIN 11.8, HEMATOCRIT 35.9. COVID TEST WAS NOT PERFORMED PER ELECTRONIC MEDICAL RECORD.'	(b) (4), (b) (6)	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 13:53:01



**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 13:53:01

**US3762131**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 13:53:42

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:42:38

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
User closed query 'Per ETRTR: According to SAE page "[...] Pilon Fracture Right tibia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:06:05
Query 'Per ETRTR: According to SAE page "[...] Pilon Fracture Right tibia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'these medications have been added in conmed page under leg fracture' (Site from CRA).	Samantha Wheeler (b) (4) (b) (4)	08 Apr 2021 21:21:43
User opened query 'Per ETRTR: According to SAE page "[...] Pilon Fracture Right tibia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 17:30:51
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 15:42:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:03:45

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:07:42
Data point term sent to Coder	System	02 Sep 2020 15:07:14
User entered 'multi vitamin'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'supplement'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'tablet (TABLET)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:50:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	02 Sep 2020 15:06:41



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'Per CDM: Dose Unit is recorded as 'Other - Pill', however, please confirm if Unit can be selected from already available options 'Tablet' or 'Capsule'. If so please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:01:06
Query 'Per CDM: Dose Unit is recorded as 'Other - Pill', however, please confirm if Unit can be selected from already available options 'Tablet' or 'Capsule'. If so please update as appropriate, else clarify.'	James Lovette (b) (4)	21 Sep 2020 13:50:41
answered with 'done' (Site from DM).	(b) (4)	
User entered empty; reason for change Data Entry Error	James Lovette (b) (4)	21 Sep 2020 13:50:29
	(b) (4)	
User opened query 'Per CDM: Dose Unit is recorded as 'Other - Pill', however, please confirm if Unit can be selected from already available options 'Tablet' or 'Capsule'. If so please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:27:01
User entered 'pill'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:06:41



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:06:41

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:06:41

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: OMEGA-3 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:30:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:30:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA-3 FATTY ACIDS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:08:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:08:47
Data point term sent to Coder User entered 'omega 3'	System (b) (4), (b) (6)	02 Sep 2020 15:08:16 02 Sep 2020 15:07:58

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:44:14
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.	(b) (4), (b) (6)	09 Nov 2020 20:12:45
' (Site from DM). Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 21:57:43
' answered with 'updated' (Site from DM). DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 21:57:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 21:57:38
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.	(b) (4), (b) (6)	22 Oct 2020 14:00:21
' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'supplement'	(b) (4), (b) (6)	02 Sep 2020 15:07:58



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'per CDM: please consider updating to TABLET from the drop down menu for dose unit' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:36:38
Query 'per CDM: please consider updating to TABLET from the drop down menu for dose unit' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 13:15:19
User entered 'tablet (TABLET)' reason for change: Data Entry Error	(b) (4)	
User opened query 'per CDM: please consider updating to TABLET from the drop down menu for dose unit' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:00:12
User entered 'Other (OTHER)'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 13:15:11
	(b) (4)	
User entered 'gelcap'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:07:58



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:07:58

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:07:58

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:09:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:09:42
Data point term sent to Coder	System	02 Sep 2020 15:09:17
User entered 'vitamin D'	(b) (4), (b) (6)	02 Sep 2020 15:08:47



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 01:19:51
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:26:59
' answered with 'will add' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 02:54:51
User entered 'deficiency'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '1000'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'IU (IU)'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'twice daily (BID)'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:08:47



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 15:08:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:08:47



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:08:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:29:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:29:01
Data point term sent to Coder	System	13 Oct 2020 13:28:26
Coding entries removed.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:37:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:37:30
Data point term sent to Coder	System	02 Sep 2020 15:10:20
User entered 'calcium'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 20:44:14
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.	(b) (4), (b) (6)	06 Nov 2020 19:47:50
' (Site from DM).		
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 21:58:03
' answered with 'updated' (Site from DM).		
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 21:57:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 21:57:57
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.	(b) (4), (b) (6)	22 Oct 2020 14:00:56
' (Site from DM).		
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	(b) (4), (b) (6)	20 Oct 2020 15:12:13
' (Site from DM).		
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Samantha Wheeler (b) (4)	13 Oct 2020 13:28:27
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered 'supplement' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 13:28:22
	(b) (4)	
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	(b) (4), (b) (6)	06 Oct 2020 02:54:58
' (Site from DM).		
User entered 'low bone density'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 07:49:46
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'no dose provided- this is what is in medical record' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 22:00:10
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:30:14
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'tablet (TABLET)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:51:10
User entered 'Other (OTHER)'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'Per CDM: Dose Unit is recorded as 'Other - Pill', however, please confirm if Unit can be selected from already available options 'Tablet' or 'Capsule'. If so please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:00:53
Query 'Per CDM: Dose Unit is recorded as 'Other - Pill', however, please confirm if Unit can be selected from already available options 'Tablet' or 'Capsule'. If so please update as appropriate, else clarify.'	James Lovette (b) (4)	21 Sep 2020 13:51:20
answered with 'done' (Site from DM).	(b) (4)	
User entered empty; reason for change Data Entry Error	James Lovette (b) (4)	21 Sep 2020 13:51:10
	(b) (4)	
User opened query 'Per CDM: Dose Unit is recorded as 'Other - Pill', however, please confirm if Unit can be selected from already available options 'Tablet' or 'Capsule'. If so please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:27:56
User entered 'pill'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 15:09:47



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:09:47



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:09:47

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:09:47

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;SODIUM FLUOROPHOSPHATE, PRODUCTSYNONYM: MONOCAL [CALCIUM CARBONATE;SODIUM FLUOROPHOSPHATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:42:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:42:45
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 13:30:29
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	13 Oct 2020 13:29:49
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Samantha Wheeler (b) (4)	13 Oct 2020 13:29:49
	(b) (4)	
User entered 'MONOCAL [monofluorophosphate, calcium carbonate]' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 13:29:43
	(b) (4)	
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	03 Sep 2020 08:01:33
	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 15:12:27
User entered 'mono cal'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

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EAB) (1725)

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**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 01:17:48
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:29:59
' answered with 'will add' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 02:55:09
User entered 'tinnitus'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '22.75 - 625'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 15:12:17



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:12:17



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:12:17

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:12:17

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 15:14:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 15:14:50
	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 15:13:34
User entered 'montelukast'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'asthma'	(b) (4), (b) (6)	02 Sep 2020 15:13:29



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:13:29



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:13:29

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:13:29

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 15:03:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:03:19
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	03 Nov 2020 22:04:01 03 Nov 2020 22:03:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:50:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:50:46
Data point term sent to Coder User entered 'magnesium'	System (b) (4), (b) (6)	02 Sep 2020 15:14:37 02 Sep 2020 15:14:26



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User closed query 'Per DM CLR: Please update the indication to reflect the location of CRAMPING. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 19:47:36
Query 'Per DM CLR: Please update the indication to reflect the location of CRAMPING. Please reconcile with Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	03 Nov 2020 22:03:16
DataPoint Un-verified.	(b) (4)	
	Samantha Wheeler (b) (4)	03 Nov 2020 22:03:12
User entered 'legs CRAMPING' reason for change:	(b) (4)	
Data Entry Error	Samantha Wheeler (b) (4)	03 Nov 2020 22:03:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User opened query 'Per DM CLR: Please update the indication to reflect the location of CRAMPING. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:44:31
User entered 'cramping'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '400'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Sep 2020 15:14:26



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '06 UNK 2020'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:14:26

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 15:14:26



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 15:14:26

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:42:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
User closed query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 08:11:00
Query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' answered with 'this medication was not prior to screening.' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	03 Nov 2020 22:08:48
User opened query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 18:10:06
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:20:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 15:20:46
Data point term sent to Coder	System	21 Sep 2020 13:55:01
User entered 'prednisone taper'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'dermatitis'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '20' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 13:32:58
User entered '1'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User closed query 'Per MM, please provide dose unit as it cannot be 'tablet'	(b) (4), (b) (6)	18 Oct 2020 20:11:03
' (Site from DM).		
Query 'Per MM, please provide dose unit as it cannot be 'tablet'	Samantha Wheeler (b) (4)	13 Oct 2020 13:33:03
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 13:32:58
	(b) (4)	
User opened query 'Per MM, please provide dose unit as it cannot be 'tablet'	(b) (4), (b) (6)	04 Oct 2020 14:44:23
' (Site from DM).		
User entered 'tablet (TABLET)'	James Lovette (b) (4)	21 Sep 2020 13:54:43
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:42:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:42:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
DataPoint Un-verified.	Samantha Wheeler (b) (4)	03 Nov 2020 22:08:08
	(b) (4)	
User entered '09 Sep 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	03 Nov 2020 22:08:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '08 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 13:54:43
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:54:43



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:54:43

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 13:54:43

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 13:39:54
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	13 Oct 2020 13:39:54
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	13 Oct 2020 13:38:53
User entered 'ibuprofen'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'injection site pain'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '200'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'as needed (PRN)'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '30 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered '02 Oct 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:20:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'pain at injection site did not meet AE reporting criteria. This injection site pain was experienced within 7 days after injection.' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	02 Dec 2020 21:24:16

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:47:33
	(b) (4), (b) (6)	03 Nov 2020 16:38:39
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 13:38:51
	(b) (4)	

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User entered empty.	System	13 Oct 2020 13:38:51

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User entered empty.	System	13 Oct 2020 13:38:51

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:41
User entered empty.	System	13 Oct 2020 13:38:51

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:42:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
User closed query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 12:19:35
Query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'no worsening was reported' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	16 Feb 2021 20:41:19
User opened query 'Per DM CLR: Was this medication added because the patient experienced a worsening or exacerbation of the medical history condition? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 09:52:14
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:52:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:52:13
Data point term sent to Coder	System	24 Nov 2020 14:50:04
User entered 'Turmeric'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 14:49:18



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered 'Inflammation of the knees'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered '1000'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 14:49:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 14:49:26
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 14:49:26
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 14:49:18
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:42:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:49:18



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered '24 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 20:44:14
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 14:49:18

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 14:49:18



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 17:58:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 17:58:16
Data point term sent to Coder	System	30 Mar 2021 17:56:39
User entered 'Acetaminophen'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE RIGHT TIBIA FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:21:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
Query 'Per DM CLR: Please note that there is no AE RIGHT TIBIA FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'this is an SAE and has been recorded' (Site from DM).	Samantha Wheeler (b) (4)	08 Apr 2021 21:20:56
User opened query 'Per DM CLR: Please note that there is no AE RIGHT TIBIA FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:15:14
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Right tibia fracture pain'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '650'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Q6 hr'	(b) (4), (b) (6)	30 Mar 2021 17:56:33



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:56:33



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:56:33

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 17:56:33

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
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: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:41:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:41:20
Data point term sent to Coder	System	30 Mar 2021 17:58:41
User entered 'ASA'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Post operative blood clot prevention'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '325'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:58:22



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'twice daily (BID)'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 17:58:22



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 17:58:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Mar 2021 17:58:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL CITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:50:27
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:50:27
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 18:31:34
User entered 'Fentanyl citrate'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User closed query 'Per DM CLR: Please note that there is no AE LEG FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:21:28
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
Query 'Per DM CLR: Please note that there is no AE LEG FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'this is recorded in the SAE section' (Site from DM).	(b) (4) Samantha Wheeler (b) (4)	08 Apr 2021 21:21:15
User opened query 'Per DM CLR: Please note that there is no AE LEG FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:16:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'leg fracture pain'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '50'	(b) (4), (b) (6)	30 Mar 2021 18:31:01



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'ug (ug)'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '20 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:31:01



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '20 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User entered empty.	System	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User entered empty.	System	30 Mar 2021 18:31:01

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:48
User entered empty.	System	30 Mar 2021 18:31:01

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 07:56:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 07:56:30
	(b) (4)	
Data point term sent to Coder	System	30 Mar 2021 18:32:35
User entered 'Hydromorphone'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:32:22



US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User closed query 'Per DM CLR: Please note that there is no AE LEG FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:21:35
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
Query 'Per DM CLR: Please note that there is no AE LEG FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'this is listed as an SAE' (Site from DM).	(b) (4) Samantha Wheeler (b) (4)	08 Apr 2021 21:21:26
User opened query 'Per DM CLR: Please note that there is no AE LEG FRACTURE PAIN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:17:05
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'leg fracture pain'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '1'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:32:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:32:22



**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '20 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered '20 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

US3762131

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:55:03
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:32:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User entered empty.	System	30 Mar 2021 18:32:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User entered empty.	System	30 Mar 2021 18:32:22

**US3762131**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:42:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:41:52
User entered empty.	System	30 Mar 2021 18:32:22



US3762131

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:42:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:32:27
User closed query 'Per ETRTR: According to SAE page "[...] Pilon Fracture Right tibia", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 16:32:20
Query 'Per ETRTR: According to SAE page "[...] Pilon Fracture Right tibia", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'updated per SAE ' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 17:58:39
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 17:58:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 17:58:29
User opened query 'Per ETRTR: According to SAE page "[...] Pilon Fracture Right tibia", a Procedure was performed for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 17:31:14
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:05:15
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 16:11:03

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:42:38**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered '20 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:27:06

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered 'CLOSED REDUCTION AND LOWER EXTREMITY EXTERNAL FIXATOR APPLICATION RIGHT TIBIA'	(b) (4), (b) (6)	30 Mar 2021 18:27:06

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Mar 2021 18:27:06

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:42:38**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:06

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:42:38**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:23
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered '22 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:27:29

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:23
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered 'REMOVE EXTERNAL FIXATOR, REMOVE ANKLE SCREWS, ORIF FIBULA AND TIBIA WITH INSERTION IM NAIL'	(b) (4), (b) (6)	30 Mar 2021 18:27:29

**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:23
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Mar 2021 18:27:29



**US3762131**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:42:38**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:23
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:32:39
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:27:29

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered		
'USA-US130-2021-MRNA-1273-P301000006'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'John'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Sanders'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '100 Medical Center Blvd'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Winston-Salem'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'NC'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '27157'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'US'	System	24 Mar 2021 14:45:58



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 13:16:07
User entered '3'	System	31 Mar 2021 13:48:04
User entered '2'	System	29 Mar 2021 14:19:54
User entered '1'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered		
'USA-US130-2021-MRNA-1273-P301000006'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'John'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Sanders'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '100 Medical Center Blvd'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Winston-Salem'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'NC'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '27157'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'US'	System	24 Mar 2021 14:45:58



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 13:16:07
User entered '3'	System	31 Mar 2021 13:48:04
User entered '2'	System	29 Mar 2021 14:19:54
User entered '1'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:42:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
User entered '24/Mar/2021 10:45'	System	24 Mar 2021 14:45:58

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:42:38

**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 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered		
'USA-US130-2021-MRNA-1273-P301000006'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'John'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Sanders'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '100 Medical Center Blvd'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Winston-Salem'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'NC'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '27157'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'US'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 13:16:07
User entered '3'	System	31 Mar 2021 13:48:04
User entered '2'	System	29 Mar 2021 14:19:54
User entered '1'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:42:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:47:08
User entered '29/Mar/2021 10:19'	System	29 Mar 2021 14:19:54

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:42:38

**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 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 17:47:08
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:47:49
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 14:19:54

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered		
'USA-US130-2021-MRNA-1273-P301000006'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'John'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Sanders'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '100 Medical Center Blvd'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Winston-Salem'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'NC'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '27157'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'US'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 13:16:07
User entered '3'	System	31 Mar 2021 13:48:04
User entered '2'	System	29 Mar 2021 14:19:54
User entered '1'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:42:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:47:08
User entered '31/Mar/2021 09:47'	System	31 Mar 2021 13:48:04

US3762131

Folder: SAE USA-US130-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:42:38

**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 18:23:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:15:48
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:47:08
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 13:48:04

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'USA-US130-2021-MRNA-1273-P301000006'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Yes (Y)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'No (N)'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'John'	System	24 Mar 2021 14:45:45



**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Sanders'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '100 Medical Center Blvd'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'Winston-Salem'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'NC'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered '27157'	System	24 Mar 2021 14:45:45

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:46:04
User entered 'US'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:42:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 13:16:07
User entered '3'	System	31 Mar 2021 13:48:04
User entered '2'	System	29 Mar 2021 14:19:54
User entered '1'	System	24 Mar 2021 14:45:58

**US3762131**

**Folder: SAE USA-US130-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:42:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:23:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:53:50
User entered '07/Apr/2021 08:15'	System	07 Apr 2021 13:16:07



US3762131

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**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 18:23:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:50
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 13:16:07