

US3762177 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:24:59

All time stamps listed in this document are displayed in GMT

US3762177

Form: Participant Creation

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

[Participant ID](#)

US3762177

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

US3762177

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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 23:09:38

Generated On: 12 Aug 2021 13:24:59

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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 23:09:38

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Date of Informed Consent (<i>dd MMM yyyy</i>)	3 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 23:09:38

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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 23:09:38

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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 Apr 2021 18:37:33

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Condition	DEPRESSION
Start date (dd MMM yyyy)	01 UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 18:37:33

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Condition	URINARY INCONTINENCE
Start date (dd MMM yyyy)	01 UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Condition	HEPATITIS A
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1959
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	JAN 1959
Stop Year (derived)	1959

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Condition	DIVERTICULITIS
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Condition	NECK PAIN
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Condition	LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Condition	CARPAL TUNNEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:26 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:26
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	142 lb
BMI (<i>xxx.x</i>)	25.20677 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:09:38

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 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 23:09:38

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Date of assessment (*dd MMM yyyy*) 03 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:09:38

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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 ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:09:38

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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 23:09:38

Generated On: 12 Aug 2021 13:24:59

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189875

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 23:09:38

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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 23:09:38

Generated On: 12 Aug 2021 13:24:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:26
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 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 23:09:38

Generated On: 12 Aug 2021 13:24:59

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)	03 SEP 2020
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:57
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 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 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:09:38

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Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:19 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:19

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 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 SEP 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

03 SEP 2020 13:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:44	03 SEP 2020 13:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

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: 12 Aug 2021 13:24:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 SEP 2020 14:50

PC Open Date & Time

03 SEP 2020 14:39

PC Close Date & Time

03 SEP 2020 17:09

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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 97.3 °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	03 SEP 2020 21:48
PC Open Date & Time	03 SEP 2020 18:04
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 18:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN 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 TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	05 SEP 2020 21:05
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN 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 TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False
PC Time Stamp	07 SEP 2020 20:22
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 21:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 20:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:51

PC Open Date & Time

03 SEP 2020 14:39

PC Close Date & Time

03 SEP 2020 17:09

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

20

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

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

Yes ☒

No ☐

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

4

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

03 SEP 2020 21:54

PC Open Date & Time

03 SEP 2020 18:04

PC Close Date & Time

04 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

65

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

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

Yes ☒

No ☐

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

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

04 SEP 2020 18:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 3
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input type="radio"/> Does not interfere with activity <input checked="" type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	95
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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. Please select one response below	None <input checked="" type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	05 SEP 2020 21:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE.	None <input type="radio"/>
Please select one response below	Does not interfere with activity <input checked="" type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	110
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input checked="" type="radio"/>
Please select one response below	Does not interfere with activity <input type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	06 SEP 2020 19:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 ☐

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

80

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 20:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 6
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input checked="" type="radio"/>
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	80
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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 <input checked="" type="radio"/>
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	08 SEP 2020 21:29
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

60

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 20:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:52
PC Open Date & Time	03 SEP 2020 14:39
PC Close Date & Time	03 SEP 2020 17:09

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:55
PC Open Date & Time	03 SEP 2020 18:04
PC Close Date & Time	04 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

		Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 20:24	
PC Open Date & Time	07 SEP 2020 12:00	
PC Close Date & Time	08 SEP 2020 11:59	

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 21:30
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

40

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

PC Time Stamp

11 SEP 2020 07:46

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

110

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

PC Time Stamp

11 SEP 2020 20:07

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

110

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

PC Time Stamp

12 SEP 2020 19:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 11

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

150

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

PC Time Stamp

13 SEP 2020 18:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 12

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

140

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

PC Time Stamp

14 SEP 2020 22:13

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 13

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

100

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

PC Time Stamp

15 SEP 2020 21:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 14

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

130

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

PC Time Stamp

16 SEP 2020 20:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 15

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

130

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

PC Time Stamp

17 SEP 2020 12:12

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 16

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

130

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

PC Time Stamp

18 SEP 2020 20:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 17

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

95

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

PC Time Stamp

19 SEP 2020 20:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 18

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

95

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

PC Time Stamp

21 SEP 2020 07:22

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 19

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

90

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

PC Time Stamp

22 SEP 2020 00:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 20

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

95

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

PC Time Stamp

23 SEP 2020 02:14

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 21

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

23 SEP 2020 23:43

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 22

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

24 SEP 2020 18:23

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 23

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

25 SEP 2020 13:42

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 24

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

26 SEP 2020 23:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 25

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

75

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

PC Time Stamp

27 SEP 2020 23:24

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 26

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

28 SEP 2020 21:53

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 27

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

29 SEP 2020 12:13

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 28

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

30 SEP 2020 22:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 29

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 30

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

02 OCT 2020 20:42

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 31

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

03 OCT 2020 21:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 32

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp 05 OCT 2020 08:59

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 33

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

05 OCT 2020 14:19

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 34

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

06 OCT 2020 19:32

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 35

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

07 OCT 2020 19:22

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 36

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

50

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

PC Time Stamp

09 OCT 2020 00:40

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 37

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

40

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

PC Time Stamp

09 OCT 2020 22:52

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 38

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

11 OCT 2020 07:18

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 07:46
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 20:07
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 19:52
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 18:24
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 SEP 2020 22:13
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 SEP 2020 21:26
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 20:43
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 12:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	18 SEP 2020 20:27
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 20:33
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 07:22
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 00:24
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 02:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 23:43
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 18:23
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 13:42
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 23:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 23:24
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 21:53
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 12:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 22:43
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 20:42
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 21:22
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 08:59
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 33
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 14:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 34
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 19:32
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 35
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 19:23
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 00:40
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 37
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 22:53
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 38

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

No ☒

Yes ☐

PC Time stamp

11 OCT 2020 07:18

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

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)	01 OCT 2020
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:34
Temperature (xxx.x)	97.8 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3762177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

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 SEVERE REACTION AFTER FIRST VACCINATION.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

01 OCT 2020 14:00

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:01	01 OCT 2020 14:01
Nasopharyngeal Swab 2	No		

US3762177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:38

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:10:12

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:10:12

Generated On: 12 Aug 2021 13:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 12:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:10:12

Generated On: 12 Aug 2021 13:24:59

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.

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:10:12

Generated On: 12 Aug 2021 13:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 NOV 2020

Collection time (00:00-23:59)

12:36 (24 HR)

Collection date and time (derived)

05 NOV 2020 12:36

US3762177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:09:39

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 00:05:08
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

12 NOV 2020 08:32:43

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	True
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
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	17 NOV 2020 11:46:43
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 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	23 NOV 2020 12:19:54
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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	28 NOV 2020 00:02:06
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 DEC 2020 08:22:37
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

16 DEC 2020 11:59:48

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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	19 DEC 2020 07:30:36
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

27 DEC 2020 02:19:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:01:36
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 08:46:25
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

19 JAN 2021 18:13:23

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 12:00:20
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

30 JAN 2021 08:43:17

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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	06 FEB 2021 07:22:47
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

13 FEB 2021 01:11:57

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 12:29:39

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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	27 FEB 2021 12:45:42
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 MAR 2021 00:02:43
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 00:10:09
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 17:59:31
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

28 MAR 2021 08:39:00

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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 APR 2021 00:02:35
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

10 APR 2021 00:02:58

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

17 APR 2021 00:08:34

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 APR 2021 14:42:28
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

02 MAY 2021 08:44:19

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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°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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2022 00:01
Patient Cloud Close Date & Time	10 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 <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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

Date and time of submission	
Patient Cloud Open Date & Time	29 OCT 2022 00:01
Patient Cloud Close Date & Time	02 NOV 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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"/>

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3762177

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:24:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	06 MAR 2021 00:03:31

US3762177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 18:33:11

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 18:33:11

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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) _____

US3762177

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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.

US3762177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

Collection date (dd MMM yyyy)	1 APR 2021
-------------------------------	------------

Collection time (00:00-23:59)	12:46 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	1 APR 2021 12:46
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US3762177

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Date of Contact	18 SEP 2020
Time of Contact	10:00
Date and Time of Contact (derived)	18 SEP 2020 10:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:37:33

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:37:33

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Date of Visit	18 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	18 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:00
Height (xxx.x)	63 in
Weight (xxx.x)	145 lb
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3762177

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 SEP 2020

US3762177

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

Visit date (dd MMM yyyy)	27 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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US3762177

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Date of updated informed consent (<i>dd MMM yyyy</i>)	27 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3762177

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3762177

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	27 JAN 2021
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 10:37
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3762177

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	27 JAN 2021
Time of assessment (00:00-23:59)	12:26 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 12:26
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3762177

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

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

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

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 27 JAN 2021

What was the treatment time? (00:00-23:59) 11:56 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 11:56

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

What was the frequency of the study treatment dosing? ONCE

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

27 JAN 2021 10:40

US3762177

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	10:43
Collection Date and Time (derived)	27 JAN 2021 10:43

US3762177

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

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 09:31
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762177

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3762177

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

09:34 (24 HR)

Collection date and time (derived)

24 FEB 2021 09:34

US3762177

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Mar 2021 17:31:28

Generated On: 12 Aug 2021 13:24:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

AEID

Adverse event

INJECTION SITE REDNESS, LEFT
ARM NON-URTICARIAL

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

03 SEP 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 OCT 2020

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

9 OCT 2020 00:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

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

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

AEID

Adverse event FATIGUE

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☒
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 04 SEP 2020

Start time (00:00-23:59) 00:00 (24 HR)

AE start date and time (derived) 04 SEP 2020 00:00

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 20 SEP 2020

End time (00:00-23:59) 00:00 (24 HR)

AE End Date and Time (derived) 20 SEP 2020 00:00

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

AEID

Adverse event

STOMACH ACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

AEID

Adverse event

INTERMITTENT BODY ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 SEP 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

04 SEP 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 NOV 2020

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

4 NOV 2020 00:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Apr 2021 18:37:32

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

AEID	
Adverse event	VOMIT
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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
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 (5)

Data signed: (b) (4) 12 Apr 2021 18:37:32

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

PT STATED SHE ATE
LEFTOVERS ON 10/26/2020 AND
HAD VOMITING ON 10/27/2020
AND STOMACH PAIN FROM
10/27/2020 UNTIL VISIT 3 WITH
HER PCP ON 11/2/2020. PCP
PRESCRIBED VENTYL PRN FOR
STOMACH PAINS AND PT TOOK
HER FIRST DOSE 11/3/2020. PCP
INDICATED TO THE PT THAT
THIS MAY BE MORE RELATED
TO HER IBS AND
DIVERTICULITIS THAN COVE
STUDY.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

AEID	
Adverse event	STOMACH PAINS
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)	27 OCT 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 (6)

Data signed: (b) (4) 12 Apr 2021 18:37:32

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

PT STATED SHE ATE
LEFTOVERS ON 10/26/2020 AND
HAD VOMITING ON 10/27/2020
AND STOMACH PAIN FROM
10/27/2020 UNTIL VISIT 3 WITH
HER PCP ON 11/2/2020. PCP
PRESCRIBED VENTYL PRN FOR
STOMACH PAINS AND PT TOOK
HER FIRST DOSE 11/3/2020. PCP
INDICATED TO THE PT THAT
THIS MAY BE MORE RELATED
TO HER IBS AND
DIVERTICULITIS THAN COVE
STUDY.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 18:37:33

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 125

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 18:37:32

Generated On: 12 Aug 2021 13:24:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 SEP 1983	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication LIOTHYRONINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 150

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 UNK 2000
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication MUSCLE ACHES

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	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)		05 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) 05 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication MUSCLE ACHES

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	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)		07 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) 07 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT BODY ACHES

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	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)		05 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)		07 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication STOMACH ACHE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication IMMIDIUM

Prophylaxis Yes ☐
No ☒

Indication STOMACH ACHE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

Name of Medication BENTYL

Prophylaxis Yes ☐
No ☒

Indication IBS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:37:32

Generated On: 12 Aug 2021 13:24:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 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"/>

US3762177

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3762177

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Apr 2021 18:37:33

Generated On: 12 Aug 2021 13:24:59

Date of dosing discontinuation (dd MMM yyyy) 03 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

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

INJECTION SITE REACTION
AE1,
AE2, AE3, AND AE4

US3762177

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:24:59

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 ☐

Audit

US3762177 (Prod: Wake Forest University Health Sciences)

US3762177

Form: Participant Creation

Generated On: 12 Aug 2021 13:24:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:42:18
User entered 'US3762177'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:34:41

US3762177

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:24:52

US3762177

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:34:42

US3762177

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Clinic (Clinic)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:24:52

US3762177

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered 'SCRN'	System	03 Sep 2020 18:24:52

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:34:43

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Per CDM: Please complete the form' (Site from DM).	(b) (4)	14 Sep 2020 16:32:23
Query 'Per CDM: Please complete the form' answered with 'Date of birth is (b) (6) 1954. At time of visit patient is 65 years old.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 11:24:24
User entered '65' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Sep 2020 11:23:41
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:22:03
User entered '65'	(b) (4), (b) (6)	11 Sep 2020 11:21:09
User opened query 'Per CDM: Please complete the form' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:52:06

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'YEARS'	System	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '66'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Sep 2020'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2020'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:34:42

US3762177

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'I'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:24:59

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:00

US3762177

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:24:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:25:00

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:26:42
Data point term sent to Coder	System	11 Sep 2020 11:25:46
User entered 'Hypothyroidism'	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 UNK 1983'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 1983'	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '1983'	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:27:42
Data point term sent to Coder	System	11 Sep 2020 11:26:47
User entered 'Depression'	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 UNK 1998'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 1998'	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '1998'	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:27:42
Data point term sent to Coder	System	11 Sep 2020 11:26:47
User entered 'Urinary Incontinence'	(b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 UNK 2018'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2018'	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2018'	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 15:41:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 15:41:18
Data point term sent to Coder	System	13 Oct 2020 15:40:01
User entered 'post menopausal'	Samantha Wheeler (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'un UNK 2000'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Samantha Wheeler (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2000'	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2000'	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:24
Data point term sent to Coder	System	05 Nov 2020 18:01:30
User entered 'Frequent Constipation'	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2010'	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2010'	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis A, LLT: Hepatitis A - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:23
Data point term sent to Coder	System	05 Nov 2020 18:01:32
User entered 'Hepatitis A'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 1959'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 1959'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:03:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:03:21
Data point term sent to Coder	System	05 Nov 2020 18:02:33
User entered 'Irritable Bowel Syndrome'	(b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2010'	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2010'	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:03:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:03:22
Data point term sent to Coder	System	05 Nov 2020 18:02:33
User entered 'Diverticulitis'	(b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2002'	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2002'	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:04:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:04:21
Data point term sent to Coder	System	05 Nov 2020 18:03:34
User entered 'Neck Pain'	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 1969'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 1969'	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '1969'	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:22
Data point term sent to Coder	System	05 Nov 2020 18:04:36
User entered 'Osteoarthritis'	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2010'	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2010'	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:20
Data point term sent to Coder	System	05 Nov 2020 18:04:36
User entered 'Osteopenia'	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2010'	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2010'	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:06:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:06:23
Data point term sent to Coder	System	05 Nov 2020 18:05:40
User entered 'Lower Back Pain'	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2012'	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2012'	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:22:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:22:21
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:07:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:07:21
Data point term sent to Coder	System	05 Nov 2020 18:06:41
User entered 'Carpal Tunnel Syndrome'	(b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2002'	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2002'	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Apr 2021 09:20:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:20:46
Data point term sent to Coder	System	09 Apr 2021 16:12:57
User entered 'botox injection cosmetic face'	Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'un UNK 2013'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '0'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'un UNK 2013'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '0'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2013'	System	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2013'	System	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'Jan 2013'	System	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:24:59

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '2013'	System	09 Apr 2021 16:12:05

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '13:26'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered '03 Sep 2020 13:26'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	11 Sep 2020 11:36:55
User entered '63' in reason for change: Data Entry Error	System	11 Sep 2020 11:36:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:36:41
User entered '63' (non-conformant).	System	11 Sep 2020 11:36:41
DataPoint set to visible.	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	11 Sep 2020 11:36:55
User entered '142' lb reason for change: Data Entry Error	System	11 Sep 2020 11:36:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 11:36:41
User entered '142' (non-conformant).	System	11 Sep 2020 11:36:41
DataPoint set to visible.	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered '25.20677'	System	11 Sep 2020 11:36:55
User entered empty.	System	11 Sep 2020 11:36:41
DataPoint set to visible.	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered 'kg/m2'	System	11 Sep 2020 11:36:55
User entered empty.	System	11 Sep 2020 11:36:41
DataPoint set to visible.	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	11 Sep 2020 11:37:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 11:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:37:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 11:36:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered 'bpm'	System	11 Sep 2020 11:37:09
User entered empty.	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered 'breaths/min'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered 'mmHg'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User entered 'mmHg'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24

US3762177

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:37:42

US3762177

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:37:42

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:27:36
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. answered with 'will update' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:38:54
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:39:57
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	(b) (4) System	13 Oct 2020 15:38:49
User opened query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	13 Oct 2020 15:38:37
User entered 'un UNK 2000' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:38:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:59

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Samantha Wheeler (b) (4)	13 Oct 2020 15:38:49
User entered '1'	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:24
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 11:53:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Samples received ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:59:00
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:19:46
User entered '03 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Clinic (Clinic)'	Samantha Wheeler (b) (4)	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'VISIT1'	System	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:54:35

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '189875'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:54:35

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:54:35

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:59

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:06:11
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:14:29
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:14:27

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '13:26'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered '03 Sep 2020 13:26'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'bpm'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'breaths/min'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '104'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '67'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '14:57'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered '03 Sep 2020 14:57'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '68'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'bpm'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '16'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'breaths/min'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '119'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '67'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:05

US3762177

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:05

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	03 Sep 2020 18:25:59
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	03 Sep 2020 18:25:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	03 Sep 2020 18:25:59
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	03 Sep 2020 18:08:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 18:08:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	03 Sep 2020 18:25:59
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	03 Sep 2020 18:08:33
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:25:59
User entered empty.	System	03 Sep 2020 18:08:33
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '14:19' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 18:25:59
User entered '14:02'	Samantha Wheeler (b) (4)	03 Sep 2020 18:08:00
	(b) (4)	
	(b) (4), (b) (6)	

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered '3 Sep 2020 14:19'	System	03 Sep 2020 18:25:59
User entered '3 Sep 2020 14:02'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4)	03 Sep 2020 18:25:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'ONCE'	System	03 Sep 2020 18:25:59
User entered empty.	System	03 Sep 2020 18:08:33
User entered 'ONCE'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:25:59
User entered empty.	System	03 Sep 2020 18:08:33
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '13:40'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered '03 Sep 2020 13:40'	System	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '13:44'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered '03 Sep 2020 13:44'	System	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered empty.	System	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:44:02

US3762177

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'I'	System	11 Sep 2020 11:44:02

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:49:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2' User entered 'Yes (Y)'	System	03 Sep 2020 18:50:26
	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2' User entered '97.7'	System	03 Sep 2020 18:50:26
	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2'	System	03 Sep 2020 18:50:26
User entered 'No (N)'	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2'	System	03 Sep 2020 18:50:26
User entered '03 Sep 2020 14:50'	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af' User entered 'Yes (Y)'	System	04 Sep 2020 01:48:40
	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af' User entered '97.3'	System	04 Sep 2020 01:48:40
	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af' User entered 'No (N)'	System	04 Sep 2020 01:48:40
	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af' User entered '03 Sep 2020 21:48'	System	04 Sep 2020 01:48:40
	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 18:04'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 2'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:48:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98'	System	04 Sep 2020 22:49:21
User entered 'Yes (Y)'	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98' User entered '98.6'	System	04 Sep 2020 22:49:21
	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98'	System	04 Sep 2020 22:49:21
User entered 'No (N)'	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98' User entered '04 Sep 2020 18:49'	System	04 Sep 2020 22:49:21
	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 3'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215' User entered 'Yes (Y)'	System	06 Sep 2020 01:06:00
	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215' User entered '97.1'	System	06 Sep 2020 01:06:00
	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered 'Yes (Y)'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
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 'omeprazole and immodium taken' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:30:28
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).	Samantha Wheeler (b) (4)	13 Oct 2020 15:16:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	(b) (4)	
User entered '1'	System	06 Sep 2020 01:06:00
	System	06 Sep 2020 01:06:00
	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215' User entered '0'	System	06 Sep 2020 01:06:00
	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered '05 Sep 2020 21:05'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 4'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:51:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:51:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637' User entered '98.5'	System	06 Sep 2020 23:52:08
	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:51:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered 'No (N)'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered '06 Sep 2020 19:52'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 5'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:21:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7' User entered 'Yes (Y)'	System	08 Sep 2020 00:22:22
	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7' User entered '97.9'	System	08 Sep 2020 00:22:22
	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7' User entered 'Yes (Y)'	System	08 Sep 2020 00:22:22
	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
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 'omeprazole and immodium taken' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:45:36
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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7' User entered '1'	Samantha Wheeler (b) (4)	13 Oct 2020 15:16:56
	(b) (4)	
	System	08 Sep 2020 00:22:22
	System	08 Sep 2020 00:22:22
	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7' User entered '0'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7' User entered '07 Sep 2020 20:22'	System	08 Sep 2020 00:22:22
	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 6'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70' User entered 'Yes (Y)'	System	09 Sep 2020 01:28:39
	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70' User entered '98.1'	System	09 Sep 2020 01:28:39
	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70' User entered 'No (N)'	System	09 Sep 2020 01:28:39
	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70' User entered '08 Sep 2020 21:28'	System	09 Sep 2020 01:28:39
	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 7'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293' User entered 'Yes (Y)'	System	10 Sep 2020 00:50:46
	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293' User entered '98.0'	System	10 Sep 2020 00:50:46
	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293'	System	10 Sep 2020 00:50:46
User entered 'No (N)'	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293' User entered '09 Sep 2020 20:50'	System	10 Sep 2020 00:50:46
	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered 'None (1)'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3' User entered 'No (N)'	System	03 Sep 2020 18:51:22
	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3' User entered 'No (N)'	System	03 Sep 2020 18:51:22
	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered 'None (1)'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3' User entered '03 Sep 2020 14:51'	System	03 Sep 2020 18:51:22
	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:50:29', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:52:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81' User entered 'Yes (Y)'	System	04 Sep 2020 01:55:02
	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:52:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81' User entered '20'	System	04 Sep 2020 01:55:02
	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:53:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'Yes (Y)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:54:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81' User entered '4'	System	04 Sep 2020 01:55:02
	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:54:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'None (1)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:54:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81' User entered '03 Sep 2020 21:54'	System	04 Sep 2020 01:55:02
	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 18:04'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 2'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'Yes (Y)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered '65'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:50:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'Yes (Y)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:52:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered '30'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:52:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'None (1)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered '04 Sep 2020 18:53'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 3'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370'	System	06 Sep 2020 01:06:44
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered 'Yes (Y)'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered '95'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered 'Yes (Y)'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered '30'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered 'None (1)'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered '05 Sep 2020 21:06'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 4'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered '110'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered '30'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'None (1)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered '06 Sep 2020 19:52'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 5'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f'	System	08 Sep 2020 00:23:20
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered 'Yes (Y)'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered '80'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered 'Yes (Y)'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered '20'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered 'None (1)'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered '07 Sep 2020 20:23'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 6'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered 'None (1)'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered 'Yes (Y)'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered '80'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered 'Yes (Y)'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered '20'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered 'None (1)'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered '08 Sep 2020 21:29'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 7'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'None (1)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'Yes (Y)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered '60'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77' User entered 'No (N)'	System	10 Sep 2020 00:51:08
	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'None (1)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77' User entered '09 Sep 2020 20:51'	System	10 Sep 2020 00:51:08
	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203' User entered 'None (0)'	System	03 Sep 2020 18:52:05
	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203' User entered 'None (0)'	System	03 Sep 2020 18:52:05
	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'No (N)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:52:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390' User entered 'None (0)'	System	04 Sep 2020 01:55:29
	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:18', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390' User entered 'None (0)'	System	04 Sep 2020 01:55:29
	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'No (N)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered '03 Sep 2020 21:55'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Sep 2020 18:04'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 2'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'Some interference with activity (2)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929' User entered 'None (0)'	System	04 Sep 2020 22:54:30
	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929' User entered 'None (0)'	System	04 Sep 2020 22:54:30
	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929' User entered 'None (0)'	System	04 Sep 2020 22:54:30
	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929' User entered 'No (N)'	System	04 Sep 2020 22:54:30
	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929' User entered '04 Sep 2020 18:54'	System	04 Sep 2020 22:54:30
	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 3'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3' User entered 'None (0)'	System	06 Sep 2020 01:07:44
	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3' User entered 'None (0)'	System	06 Sep 2020 01:07:44
	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3' User entered 'None (0)'	System	06 Sep 2020 01:07:44
	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3' User entered 'No (N)'	System	06 Sep 2020 01:07:44
	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3' User entered '05 Sep 2020 21:07'	System	06 Sep 2020 01:07:44
	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 4'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d' User entered 'None (0)'	System	06 Sep 2020 23:53:34
	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d' User entered 'None (0)'	System	06 Sep 2020 23:53:34
	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d' User entered 'None (0)'	System	06 Sep 2020 23:53:34
	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:10', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d' User entered 'None (0)'	System	06 Sep 2020 23:53:34
	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d' User entered 'No (N)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d' User entered '06 Sep 2020 19:53'	System	06 Sep 2020 23:53:34
	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 5'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered 'None (0)'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:29', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered 'No interference with activity (1)'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered 'No interference with activity (1)'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered 'None (0)'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered 'None (0)'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered 'No (N)'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:24:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b' User entered '07 Sep 2020 20:24'	System	08 Sep 2020 00:24:04
	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 6'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0' User entered 'None (0)'	System	09 Sep 2020 01:30:07
	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0' User entered 'None (0)'	System	09 Sep 2020 01:30:07
	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0' User entered 'None (0)'	System	09 Sep 2020 01:30:07
	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0' User entered 'No (N)'	System	09 Sep 2020 01:30:07
	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:30:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0' User entered '08 Sep 2020 21:30'	System	09 Sep 2020 01:30:07
	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 7'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594' User entered 'None (0)'	System	10 Sep 2020 00:51:44
	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594' User entered 'None (0)'	System	10 Sep 2020 00:51:44
	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594' User entered 'None (0)'	System	10 Sep 2020 00:51:44
	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:31', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594' User entered 'None (0)'	System	10 Sep 2020 00:51:44
	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'No (N)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594' User entered '09 Sep 2020 20:51'	System	10 Sep 2020 00:51:44
	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	09 Sep 2020 01:29:25
User entered 'Day 8'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:45:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2cf730f5-b117-49c5-91f1-71f8b0a6b4b1' User entered 'Yes (Y)'	System	11 Sep 2020 11:46:07
	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:45:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2cf730f5-b117-49c5-91f1-71f8b0a6b4b1' User entered '40'	System	11 Sep 2020 11:46:07
	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:46:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2cf730f5-b117-49c5-91f1-71f8b0a6b4b1' User entered '11 Sep 2020 07:46'	System	11 Sep 2020 11:46:07
	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	10 Sep 2020 00:51:08
User entered 'Day 9'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:06:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0aa7554e-3f37-43d1-b57a-d5670998b09c' User entered 'Yes (Y)'	System	12 Sep 2020 00:07:05
	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:06:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0aa7554e-3f37-43d1-b57a-d5670998b09c' User entered '110'	System	12 Sep 2020 00:07:05
	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:07:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0aa7554e-3f37-43d1-b57a-d5670998b09c' User entered '11 Sep 2020 20:07'	System	12 Sep 2020 00:07:05
	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	11 Sep 2020 11:46:07
User entered 'Day 10'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:29', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c4403575-4b98-4226-ba0e-2b40125f3721' User entered 'Yes (Y)'	System	12 Sep 2020 23:52:53
	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c4403575-4b98-4226-ba0e-2b40125f3721' User entered '110'	System	12 Sep 2020 23:52:53
	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c4403575-4b98-4226-ba0e-2b40125f3721' User entered '12 Sep 2020 19:52'	System	12 Sep 2020 23:52:53
	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	12 Sep 2020 00:07:05
User entered 'Day 11'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6b84ad84-14f2-4a60-8452-29f78ce03951' User entered 'Yes (Y)'	System	13 Sep 2020 22:24:55
	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6b84ad84-14f2-4a60-8452-29f78ce03951' User entered '150'	System	13 Sep 2020 22:24:55
	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6b84ad84-14f2-4a60-8452-29f78ce03951' User entered '13 Sep 2020 18:24'	System	13 Sep 2020 22:24:55
	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	12 Sep 2020 23:52:53
User entered 'Day 12'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0ce56ef6-080d-431b-bc99-2c735da07837' User entered 'Yes (Y)'	System	15 Sep 2020 02:13:46
	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0ce56ef6-080d-431b-bc99-2c735da07837' User entered '140'	System	15 Sep 2020 02:13:46
	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0ce56ef6-080d-431b-bc99-2c735da07837' User entered '14 Sep 2020 22:13'	System	15 Sep 2020 02:13:46
	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	13 Sep 2020 22:24:55
User entered 'Day 13'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ce76890-ef97-47a0-b661-ab32642b83da' User entered 'Yes (Y)'	System	16 Sep 2020 01:26:35
	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ce76890-ef97-47a0-b661-ab32642b83da' User entered '100'	System	16 Sep 2020 01:26:35
	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ce76890-ef97-47a0-b661-ab32642b83da' User entered '15 Sep 2020 21:25'	System	16 Sep 2020 01:26:35
	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	15 Sep 2020 02:13:46
User entered 'Day 14'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bffd9070-11d2-4989-9a5a-8f302cf3edcd' User entered 'Yes (Y)'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bffd9070-11d2-4989-9a5a-8f302cf3edcd' User entered '130'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bffd9070-11d2-4989-9a5a-8f302cf3edcd' User entered '16 Sep 2020 20:43'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	16 Sep 2020 01:26:35
User entered 'Day 15'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '11d3a7bb-967f-4b49-a8c0-ef9ef24fdb49' User entered 'Yes (Y)'	System	17 Sep 2020 16:12:17
	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:10', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '11d3a7bb-967f-4b49-a8c0-ef9ef24fdb49' User entered '130'	System	17 Sep 2020 16:12:17
	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '11d3a7bb-967f-4b49-a8c0-ef9ef24fdb49' User entered '17 Sep 2020 12:12'	System	17 Sep 2020 16:12:17
	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	17 Sep 2020 00:43:47
User entered 'Day 16'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cf3ac124-6f83-4d03-a965-9687da4689e9' User entered 'Yes (Y)'	System	19 Sep 2020 00:27:15
	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cf3ac124-6f83-4d03-a965-9687da4689e9' User entered '130'	System	19 Sep 2020 00:27:15
	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cf3ac124-6f83-4d03-a965-9687da4689e9' User entered '18 Sep 2020 20:27'	System	19 Sep 2020 00:27:15
	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	17 Sep 2020 16:12:17
User entered 'Day 17'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:32:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ca2ad44c-393d-4f5e-9aae-11b7c9d23fc2'	System	20 Sep 2020 00:32:59
User entered 'Yes (Y)'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:32:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ca2ad44c-393d-4f5e-9aae-11b7c9d23fc2' User entered '95'	System	20 Sep 2020 00:32:59
	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:32:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ca2ad44c-393d-4f5e-9aae-11b7c9d23fc2' User entered '19 Sep 2020 20:32'	System	20 Sep 2020 00:32:59
	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	19 Sep 2020 00:27:15
User entered 'Day 18'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '06f6bc1c-72a9-4476-bf92-cbb8a87ebe23' User entered 'Yes (Y)'	System	21 Sep 2020 11:22:44
	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '06f6bc1c-72a9-4476-bf92-cbb8a87ebe23' User entered '95'	System	21 Sep 2020 11:22:44
	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '06f6bc1c-72a9-4476-bf92-cbb8a87ebe23' User entered '21 Sep 2020 07:22'	System	21 Sep 2020 11:22:44
	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	20 Sep 2020 00:32:59
User entered 'Day 19'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8f42d2a7-d546-4bdb-a5c1-f3d21ec14f75'	System	22 Sep 2020 04:24:45
User entered 'Yes (Y)'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8f42d2a7-d546-4bdb-a5c1-f3d21ec14f75' User entered '90'	System	22 Sep 2020 04:24:45
	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8f42d2a7-d546-4bdb-a5c1-f3d21ec14f75'	System	22 Sep 2020 04:24:45
User entered '22 Sep 2020 00:24'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	21 Sep 2020 11:22:44
User entered 'Day 20'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:10', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e79d9fa7-c864-4a43-8087-44e0077f8929' User entered 'Yes (Y)'	System	23 Sep 2020 06:14:20
	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:14', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e79d9fa7-c864-4a43-8087-44e0077f8929' User entered '95'	System	23 Sep 2020 06:14:20
	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e79d9fa7-c864-4a43-8087-44e0077f8929' User entered '23 Sep 2020 02:14'	System	23 Sep 2020 06:14:20
	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	22 Sep 2020 04:24:45
User entered 'Day 21'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3536a5a7-97cc-488e-a0b1-fa08cf4aef77'	System	24 Sep 2020 03:43:40
User entered 'Yes (Y)'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3536a5a7-97cc-488e-a0b1-fa08cf4aef77' User entered '80'	System	24 Sep 2020 03:43:40
	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3536a5a7-97cc-488e-a0b1-fa08cf4aef77'	System	24 Sep 2020 03:43:40
User entered '23 Sep 2020 23:43'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	23 Sep 2020 06:14:20
User entered 'Day 22'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '48c0be3b-3fdd-4487-be97-24fbe17af0a6' User entered 'Yes (Y)'	System	24 Sep 2020 22:23:42
	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '48c0be3b-3fdd-4487-be97-24fbe17af0a6' User entered '80'	System	24 Sep 2020 22:23:42
	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '48c0be3b-3fdd-4487-be97-24fbe17af0a6' User entered '24 Sep 2020 18:23'	System	24 Sep 2020 22:23:42
	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	24 Sep 2020 03:43:40
User entered 'Day 23'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:41:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a70b4ad7-6440-47da-9706-5109ef2e93d4' User entered 'Yes (Y)'	System	25 Sep 2020 17:42:05
	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:41:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a70b4ad7-6440-47da-9706-5109ef2e93d4' User entered '70'	System	25 Sep 2020 17:42:05
	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:42:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a70b4ad7-6440-47da-9706-5109ef2e93d4' User entered '25 Sep 2020 13:42'	System	25 Sep 2020 17:42:05
	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	24 Sep 2020 22:23:42
User entered 'Day 24'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd2183ccb-2a6c-4b5e-8950-f9c822eed327'	System	27 Sep 2020 03:02:16
User entered 'Yes (Y)'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd2183ccb-2a6c-4b5e-8950-f9c822eed327' User entered '70'	System	27 Sep 2020 03:02:16
	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd2183ccb-2a6c-4b5e-8950-f9c822eed327' User entered '26 Sep 2020 23:02'	System	27 Sep 2020 03:02:16
	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	25 Sep 2020 17:42:05
User entered 'Day 25'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c347f892-81d2-4076-a1e0-ab5b0c559027' User entered 'Yes (Y)'	System	28 Sep 2020 03:24:19
	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c347f892-81d2-4076-a1e0-ab5b0c559027' User entered '75'	System	28 Sep 2020 03:24:19
	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c347f892-81d2-4076-a1e0-ab5b0c559027' User entered '27 Sep 2020 23:24'	System	28 Sep 2020 03:24:19
	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	27 Sep 2020 03:02:16
User entered 'Day 26'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:31', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8d627b8-6e57-4ee6-a498-42ce44de39e8' User entered 'Yes (Y)'	System	29 Sep 2020 01:53:44
	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8d627b8-6e57-4ee6-a498-42ce44de39e8' User entered '70'	System	29 Sep 2020 01:53:44
	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8d627b8-6e57-4ee6-a498-42ce44de39e8' User entered '28 Sep 2020 21:53'	System	29 Sep 2020 01:53:44
	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	28 Sep 2020 03:24:19
User entered 'Day 27'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '39b533c1-d2b8-43df-9cc4-839d966679b6' User entered 'Yes (Y)'	System	29 Sep 2020 16:13:36
	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '39b533c1-d2b8-43df-9cc4-839d966679b6' User entered '70'	System	29 Sep 2020 16:13:36
	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '39b533c1-d2b8-43df-9cc4-839d966679b6' User entered '29 Sep 2020 12:13'	System	29 Sep 2020 16:13:36
	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	29 Sep 2020 01:53:44
User entered 'Day 28'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8b9a74d4-d686-49c5-ab1a-dc67450c134d' User entered 'Yes (Y)'	System	01 Oct 2020 02:43:37
	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8b9a74d4-d686-49c5-ab1a-dc67450c134d' User entered '70'	System	01 Oct 2020 02:43:37
	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8b9a74d4-d686-49c5-ab1a-dc67450c134d' User entered '30 Sep 2020 22:43'	System	01 Oct 2020 02:43:37
	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	29 Sep 2020 16:13:36
User entered 'Day 29'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	01 Oct 2020 02:43:37
User entered 'Day 30'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'b683db76-04b6-4197-a16c-f88bf98e6887' User entered 'Yes (Y)'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'b683db76-04b6-4197-a16c-f88bf98e6887' User entered '80'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'b683db76-04b6-4197-a16c-f88bf98e6887' User entered '02 Oct 2020 20:42'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 31'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:31', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ea17fbd2-d25d-4393-af92-88e9719c5314' User entered 'Yes (Y)'	System	04 Oct 2020 01:22:42
	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ea17fbd2-d25d-4393-af92-88e9719c5314' User entered '80'	System	04 Oct 2020 01:22:42
	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ea17fbd2-d25d-4393-af92-88e9719c5314' User entered '03 Oct 2020 21:22'	System	04 Oct 2020 01:22:42
	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 32'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:58:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cb314901-fd0d-4d0f-90d6-9e971c1a4da5' User entered 'Yes (Y)'	System	05 Oct 2020 12:59:08
	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cb314901-fd0d-4d0f-90d6-9e971c1a4da5' User entered '70'	System	05 Oct 2020 12:59:08
	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cb314901-fd0d-4d0f-90d6-9e971c1a4da5' User entered '05 Oct 2020 08:59'	System	05 Oct 2020 12:59:08
	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	04 Oct 2020 01:22:42
User entered 'Day 33'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9855626c-c501-4c7e-b9eb-66837e428737' User entered 'Yes (Y)'	System	05 Oct 2020 18:19:28
	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9855626c-c501-4c7e-b9eb-66837e428737' User entered '70'	System	05 Oct 2020 18:19:28
	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9855626c-c501-4c7e-b9eb-66837e428737' User entered '05 Oct 2020 14:19'	System	05 Oct 2020 18:19:28
	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	05 Oct 2020 12:59:08
User entered 'Day 34'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '80464290-40bd-44c9-94c7-74d4f6b965aa' User entered 'Yes (Y)'	System	06 Oct 2020 23:32:50
	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '80464290-40bd-44c9-94c7-74d4f6b965aa' User entered '70'	System	06 Oct 2020 23:32:50
	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '80464290-40bd-44c9-94c7-74d4f6b965aa' User entered '06 Oct 2020 19:32'	System	06 Oct 2020 23:32:50
	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	05 Oct 2020 18:19:28
User entered 'Day 35'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:22:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f2389d1-4943-45b3-90ef-8b13baef6141' User entered 'Yes (Y)'	System	07 Oct 2020 23:23:01
	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:22:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f2389d1-4943-45b3-90ef-8b13baef6141' User entered '70'	System	07 Oct 2020 23:23:01
	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:22:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f2389d1-4943-45b3-90ef-8b13baef6141' User entered '07 Oct 2020 19:22'	System	07 Oct 2020 23:23:01
	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	06 Oct 2020 23:32:50
User entered 'Day 36'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '373253f4-681c-4a3a-a0b8-49ca3187fbf3' User entered 'Yes (Y)'	System	09 Oct 2020 04:40:34
	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '373253f4-681c-4a3a-a0b8-49ca3187fbf3'	System	09 Oct 2020 04:40:34
User entered '50'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '373253f4-681c-4a3a-a0b8-49ca3187fbf3' User entered '09 Oct 2020 00:40'	System	09 Oct 2020 04:40:34
	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	07 Oct 2020 23:23:01
User entered 'Day 37'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:52:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '38d50110-0408-4abc-aaac-32fdcffa32ef' User entered 'Yes (Y)'	System	10 Oct 2020 02:53:02
	System	10 Oct 2020 02:53:02

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:52:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '38d50110-0408-4abc-aaac-32fdcffa32ef' User entered '40'	System	10 Oct 2020 02:53:02
	System	10 Oct 2020 02:53:02

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:52:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '38d50110-0408-4abc-aaac-32fdcffa32ef' User entered '09 Oct 2020 22:52'	System	10 Oct 2020 02:53:02
	System	10 Oct 2020 02:53:02

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	09 Oct 2020 04:40:34
User entered 'Day 38'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 12 Aug 2021 13:24:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40c62073-aae0-4916-aa9b-415a939f69a0' User entered 'No (N)'	System	11 Oct 2020 11:18:49
	System	11 Oct 2020 11:18:49

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 12 Aug 2021 13:24:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40c62073-aae0-4916-aa9b-415a939f69a0' User entered '11 Oct 2020 07:18'	System	11 Oct 2020 11:18:49
	System	11 Oct 2020 11:18:49

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	09 Sep 2020 01:29:25
User entered 'Day 8'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:46:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ab0c648-0870-4c2b-832b-37a38bd77b65'	System	11 Sep 2020 11:46:13
User entered 'No (N)'	System	11 Sep 2020 11:46:13

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:46:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ab0c648-0870-4c2b-832b-37a38bd77b65' User entered '11 Sep 2020 07:46'	System	11 Sep 2020 11:46:13
	System	11 Sep 2020 11:46:13

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	10 Sep 2020 00:51:08
User entered 'Day 9'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:07:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f6a452b-6903-4e9a-ad85-dc3dc6dc0de0' User entered 'No (N)'	System	12 Sep 2020 00:07:17
	System	12 Sep 2020 00:07:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:07:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f6a452b-6903-4e9a-ad85-dc3dc6dc0de0' User entered '11 Sep 2020 20:07'	System	12 Sep 2020 00:07:17
	System	12 Sep 2020 00:07:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	11 Sep 2020 11:46:07
User entered 'Day 10'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f8e0bae-3d6c-400f-a877-6ade263139a8'	System	12 Sep 2020 23:52:59
User entered 'No (N)'	System	12 Sep 2020 23:52:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f8e0bae-3d6c-400f-a877-6ade263139a8' User entered '12 Sep 2020 19:52'	System	12 Sep 2020 23:52:59
	System	12 Sep 2020 23:52:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	12 Sep 2020 00:07:05
User entered 'Day 11'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0eef9eb6-172b-40d1-ab98-5ad2fdc47a3c' User entered 'No (N)'	System	13 Sep 2020 22:25:02
	System	13 Sep 2020 22:25:02

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0eef9eb6-172b-40d1-ab98-5ad2fdc47a3c' User entered '13 Sep 2020 18:24'	System	13 Sep 2020 22:25:02
	System	13 Sep 2020 22:25:02

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	12 Sep 2020 23:52:53
User entered 'Day 12'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f66890d5-0ea9-4053-a16b-892be3f66b7a' User entered 'No (N)'	System	15 Sep 2020 02:13:52
	System	15 Sep 2020 02:13:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f66890d5-0ea9-4053-a16b-892be3f66b7a' User entered '14 Sep 2020 22:13'	System	15 Sep 2020 02:13:52
	System	15 Sep 2020 02:13:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	13 Sep 2020 22:24:55
User entered 'Day 13'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f8b6a8a4-ab78-4cd9-896d-96503f0770ae' User entered 'No (N)'	System	16 Sep 2020 01:26:36
	System	16 Sep 2020 01:26:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:26:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f8b6a8a4-ab78-4cd9-896d-96503f0770ae' User entered '15 Sep 2020 21:26'	System	16 Sep 2020 01:26:36
	System	16 Sep 2020 01:26:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	15 Sep 2020 02:13:46
User entered 'Day 14'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '49337e90-c55d-410c-8a9c-d854dbf45fc9' User entered 'No (N)'	System	17 Sep 2020 00:43:53
	System	17 Sep 2020 00:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '49337e90-c55d-410c-8a9c-d854dbf45fc9' User entered '16 Sep 2020 20:43'	System	17 Sep 2020 00:43:53
	System	17 Sep 2020 00:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	16 Sep 2020 01:26:35
User entered 'Day 15'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '94fa559e-0cc1-468c-8d37-ed2e5022609f' User entered 'No (N)'	System	17 Sep 2020 16:12:27
	System	17 Sep 2020 16:12:27

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '94fa559e-0cc1-468c-8d37-ed2e5022609f' User entered '17 Sep 2020 12:12'	System	17 Sep 2020 16:12:27
	System	17 Sep 2020 16:12:27

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	17 Sep 2020 00:43:47
User entered 'Day 16'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '33e2e4d9-05d4-4554-a314-f53b8e1446b8' User entered 'Yes (Y)'	System	19 Sep 2020 00:27:32
	System	19 Sep 2020 00:27:32

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '33e2e4d9-05d4-4554-a314-f53b8e1446b8' User entered '18 Sep 2020 20:27'	System	19 Sep 2020 00:27:32
	System	19 Sep 2020 00:27:32

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	17 Sep 2020 16:12:17
User entered 'Day 17'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:33:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'af3692d8-3509-46a3-b1f2-ac06487afe7b' User entered 'No (N)'	System	20 Sep 2020 00:33:10
	System	20 Sep 2020 00:33:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:33:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'af3692d8-3509-46a3-b1f2-ac06487afe7b' User entered '19 Sep 2020 20:33'	System	20 Sep 2020 00:33:10
	System	20 Sep 2020 00:33:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	19 Sep 2020 00:27:15
User entered 'Day 18'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'efb45064-ddd0-46e3-9925-a257ce5f6506'	System	21 Sep 2020 11:22:52
User entered 'No (N)'	System	21 Sep 2020 11:22:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'efb45064-ddd0-46e3-9925-a257ce5f6506' User entered '21 Sep 2020 07:22'	System	21 Sep 2020 11:22:52
	System	21 Sep 2020 11:22:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	20 Sep 2020 00:32:59
User entered 'Day 19'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ecdcd5-7454-44e8-8278-3b346ab39fc6' User entered 'No (N)'	System	22 Sep 2020 04:24:51
	System	22 Sep 2020 04:24:51

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ecdcd5-7454-44e8-8278-3b346ab39fc6' User entered '22 Sep 2020 00:24'	System	22 Sep 2020 04:24:51
	System	22 Sep 2020 04:24:51

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	21 Sep 2020 11:22:44
User entered 'Day 20'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '67e72831-8509-466b-99b2-5e51a79f234d' User entered 'No (N)'	System	23 Sep 2020 06:14:26
	System	23 Sep 2020 06:14:26

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '67e72831-8509-466b-99b2-5e51a79f234d' User entered '23 Sep 2020 02:14'	System	23 Sep 2020 06:14:26
	System	23 Sep 2020 06:14:26

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	22 Sep 2020 04:24:45
User entered 'Day 21'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '28790100-b6ce-4e7b-8159-7ed3692466df' User entered 'No (N)'	System	24 Sep 2020 03:43:53
	System	24 Sep 2020 03:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '28790100-b6ce-4e7b-8159-7ed3692466df' User entered '23 Sep 2020 23:43'	System	24 Sep 2020 03:43:53
	System	24 Sep 2020 03:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	23 Sep 2020 06:14:20
User entered 'Day 22'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0e9f3e37-46cf-444e-80f6-606a2d55f0c8' User entered 'No (N)'	System	24 Sep 2020 22:23:50
	System	24 Sep 2020 22:23:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0e9f3e37-46cf-444e-80f6-606a2d55f0c8' User entered '24 Sep 2020 18:23'	System	24 Sep 2020 22:23:50
	System	24 Sep 2020 22:23:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	24 Sep 2020 03:43:40
User entered 'Day 23'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:42:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cc0cbff1-97d0-429b-bab6-5e478ffe5ca8'	System	25 Sep 2020 17:42:11
User entered 'No (N)'	System	25 Sep 2020 17:42:11

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:42:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cc0cbff1-97d0-429b-bab6-5e478ffe5ca8' User entered '25 Sep 2020 13:42'	System	25 Sep 2020 17:42:11
	System	25 Sep 2020 17:42:11

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	24 Sep 2020 22:23:42
User entered 'Day 24'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ed3e8d9b-63bd-45cf-a865-b139994594c4' User entered 'No (N)'	System	27 Sep 2020 03:02:21
	System	27 Sep 2020 03:02:21

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ed3e8d9b-63bd-45cf-a865-b139994594c4' User entered '26 Sep 2020 23:02'	System	27 Sep 2020 03:02:21
	System	27 Sep 2020 03:02:21

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	25 Sep 2020 17:42:05
User entered 'Day 25'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1882171e-3006-4a7f-9b26-d3a2bf2d8fd6'	System	28 Sep 2020 03:24:29
User entered 'No (N)'	System	28 Sep 2020 03:24:29

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1882171e-3006-4a7f-9b26-d3a2bf2d8fd6' User entered '27 Sep 2020 23:24'	System	28 Sep 2020 03:24:29
	System	28 Sep 2020 03:24:29

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	27 Sep 2020 03:02:16
User entered 'Day 26'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a1010553-721a-4437-b737-b68b3f5d6f3c' User entered 'No (N)'	System	29 Sep 2020 01:53:52
	System	29 Sep 2020 01:53:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a1010553-721a-4437-b737-b68b3f5d6f3c' User entered '28 Sep 2020 21:53'	System	29 Sep 2020 01:53:52
	System	29 Sep 2020 01:53:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	28 Sep 2020 03:24:19
User entered 'Day 27'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '829bd62b-2039-4d4b-9862-c8e622dfe8cb' User entered 'No (N)'	System	29 Sep 2020 16:13:39
	System	29 Sep 2020 16:13:39

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '829bd62b-2039-4d4b-9862-c8e622dfe8cb' User entered '29 Sep 2020 12:13'	System	29 Sep 2020 16:13:39
	System	29 Sep 2020 16:13:39

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	29 Sep 2020 01:53:44
User entered 'Day 28'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2b485b4d-34c5-422a-85b0-9d211010e91f' User entered 'No (N)'	System	01 Oct 2020 02:43:46
	System	01 Oct 2020 02:43:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2b485b4d-34c5-422a-85b0-9d211010e91f' User entered '30 Sep 2020 22:43'	System	01 Oct 2020 02:43:46
	System	01 Oct 2020 02:43:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	29 Sep 2020 16:13:36
User entered 'Day 29'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	01 Oct 2020 02:43:37
User entered 'Day 30'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'df083d42-32f6-42fa-825a-6d7f39ab2ae1' User entered 'No (N)'	System	03 Oct 2020 00:42:38
	System	03 Oct 2020 00:42:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'df083d42-32f6-42fa-825a-6d7f39ab2ae1' User entered '02 Oct 2020 20:42'	System	03 Oct 2020 00:42:38
	System	03 Oct 2020 00:42:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 31'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ad87883-c7cd-4c7e-b196-a22afc64b880' User entered 'No (N)'	System	04 Oct 2020 01:22:50
	System	04 Oct 2020 01:22:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ad87883-c7cd-4c7e-b196-a22afc64b880' User entered '03 Oct 2020 21:22'	System	04 Oct 2020 01:22:50
	System	04 Oct 2020 01:22:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '03 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 32'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3dd75af2-1ada-4765-a4ae-609d1e868b84' User entered 'No (N)'	System	05 Oct 2020 12:59:20
	System	05 Oct 2020 12:59:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:14', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3dd75af2-1ada-4765-a4ae-609d1e868b84' User entered '05 Oct 2020 08:59'	System	05 Oct 2020 12:59:20
	System	05 Oct 2020 12:59:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	04 Oct 2020 01:22:42
User entered 'Day 33'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0daeb8e5-04cc-4977-8101-7ffd8572199e' User entered 'No (N)'	System	05 Oct 2020 18:19:34
	System	05 Oct 2020 18:19:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0daeb8e5-04cc-4977-8101-7ffd8572199e' User entered '05 Oct 2020 14:19'	System	05 Oct 2020 18:19:34
	System	05 Oct 2020 18:19:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	05 Oct 2020 12:59:08
User entered 'Day 34'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '32874508-beec-4a7c-8afe-9576e32b3c09' User entered 'No (N)'	System	06 Oct 2020 23:32:57
	System	06 Oct 2020 23:32:57

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '32874508-beec-4a7c-8afe-9576e32b3c09' User entered '06 Oct 2020 19:32'	System	06 Oct 2020 23:32:57
	System	06 Oct 2020 23:32:57

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	05 Oct 2020 18:19:28
User entered 'Day 35'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:23:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bd819cb5-6c03-4d73-a104-e364c75ebc43' User entered 'No (N)'	System	07 Oct 2020 23:23:08
	System	07 Oct 2020 23:23:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:23:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bd819cb5-6c03-4d73-a104-e364c75ebc43' User entered '07 Oct 2020 19:23'	System	07 Oct 2020 23:23:08
	System	07 Oct 2020 23:23:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	06 Oct 2020 23:32:50
User entered 'Day 36'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '664c5b9d-06c6-4487-94b7-ca0aa74572f5' User entered 'No (N)'	System	09 Oct 2020 04:40:38
	System	09 Oct 2020 04:40:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '664c5b9d-06c6-4487-94b7-ca0aa74572f5' User entered '09 Oct 2020 00:40'	System	09 Oct 2020 04:40:38
	System	09 Oct 2020 04:40:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	07 Oct 2020 23:23:01
User entered 'Day 37'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:53:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd28f5600-091a-42c3-8ae4-9e0abec4f4af' User entered 'No (N)'	System	10 Oct 2020 02:53:10
	System	10 Oct 2020 02:53:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:53:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd28f5600-091a-42c3-8ae4-9e0abec4f4af' User entered '09 Oct 2020 22:53'	System	10 Oct 2020 02:53:10
	System	10 Oct 2020 02:53:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	09 Oct 2020 04:40:34
User entered 'Day 38'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a78d3e51-8595-4d3c-a286-a4d916f90a29' User entered 'No (N)'	System	11 Oct 2020 11:18:58
	System	11 Oct 2020 11:18:58

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 12 Aug 2021 13:24:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a78d3e51-8595-4d3c-a286-a4d916f90a29' User entered '11 Oct 2020 07:18'	System	11 Oct 2020 11:18:58
	System	11 Oct 2020 11:18:58

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 12 Aug 2021 13:24:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 12 Aug 2021 13:24:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:40:34

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '10 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	James Lovette (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 13:58:28

US3762177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'I'	System	21 Sep 2020 13:58:28

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Per SARS-CoV-2 Lab Recon: it appears GCL has an Illness sample dated 18SEP2020 which has not been received by GCL; however there is no record in EDC. Please reconcile and make all appropriate updates or clarify. If shipped already, please provide air bill tracker number' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 09:16:29
Query 'Per SARS-CoV-2 Lab Recon: it appears GCL Samantha Wheeler has an Illness sample dated 18SEP2020 which has not been received by GCL; however there is no record in EDC. Please reconcile and make all appropriate updates or clarify. If shipped already, please provide air bill tracker number' answered with 'ADDED' (Site from DM).	(b) (4) (b) (4)	13 Oct 2020 15:38:05
User opened query 'Per SARS-CoV-2 Lab Recon: it appears GCL has an Illness sample dated 18SEP2020 which has not been received by GCL; however there is no record in EDC. Please reconcile and make all appropriate updates or clarify. If shipped already, please provide air bill tracker number' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:09:39
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '17 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:04:44

US3762177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:21:47
User entered 'I'	System	21 Sep 2020 14:04:44

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:42:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'date correct' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	24 Oct 2020 23:16:12
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:12:25
User entered '24 Sep 2020'	Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:20:03

US3762177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered 'I'	System	08 Oct 2020 13:20:03

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Clinic (Clinic)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'VISIT2'	System	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User accepted default value 'Pre-Dose (PREDOSE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '13:34'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered '01 Oct 2020 13:34'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '97.8' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '75'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'bpm'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '16'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'breaths/min'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '119'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'mmHg'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '77'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'mmHg'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User accepted default value 'Post-Dose (POSTDOSE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:25:13

US3762177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:25:13

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User closed query 'Per CDM RQ: Please complete the dose discontinuation form located in End of Study folder. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 06:42:24
Query 'Per CDM RQ: Please complete the dose discontinuation form located in End of Study folder. Thank you. ' answered with 'this has been completed' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	25 Nov 2020 18:53:17
User opened query 'Per CDM RQ: Please complete the dose discontinuation form located in End of Study folder. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:49:16
User closed query 'Per CDM: It should only be one (1) record as the event that lead to IP withdrawal similar to fatal. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:49:16
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
Query 'Per CDM: It should only be one (1) record as the event that lead to IP withdrawal similar to fatal. Please review and reconcile.' answered with 'please clarify query? Should we remove exposure page? Patient did not receive second injection due to reactions from the first injection- this was PI decision. Please clarify how we should handle.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:47:47
User opened query 'Per CDM: It should only be one (1) record as the event that lead to IP withdrawal similar to fatal. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:52:58
User closed query 'Per CDM: Reason noted. However, No AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:52:58

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

If No, reason not given

Audit	User	Time (GMT)
Query 'Per CDM: Reason noted. However, No AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' answered with 'subject had many AE's that caused discontinuation of IP. Should we put this on every AE from first injection?' (Site from DM).	Samantha Wheeler (b) (4)	10 Nov 2020 19:08:52
User opened query 'Per CDM: Reason noted. However, No AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:57
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered 'Severe reaction after first vaccination.'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '14:00'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered '01 Oct 2020 14:00'	System	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '01 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '14:01'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered '01 Oct 2020 14:01'	System	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered empty.	System	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:01

US3762177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered 'I'	System	22 Oct 2020 21:27:01

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '08 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:25

US3762177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered 'I'	System	22 Oct 2020 21:27:25

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '15 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:47

US3762177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered 'I'	System	22 Oct 2020 21:27:47

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered '22 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:10

US3762177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered 'I'	System	22 Oct 2020 21:28:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '05 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered 'Clinic (Clinic)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'VISIT3'	System	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '05 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '12:32'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered '05 Nov 2020 12:32'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '98.0' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '72'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'bpm'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '17'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'breaths/min'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '122'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'mmHg'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '74'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'mmHg'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13

US3762177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:53

US3762177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:53

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '05 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:10:12
User entered '12:36'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered '05 Nov 2020 12:36'	System	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:39
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:12

US3762177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:59:13
User entered 'I'	System	09 Nov 2020 14:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 64'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-03T00:04:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cbd2a3bd-35ae-4d2d-b122-b15b092e8fae' User entered 'No (N)'	System	03 Nov 2020 05:05:12
	System	03 Nov 2020 05:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-03T00:05:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cbd2a3bd-35ae-4d2d-b122-b15b092e8fae' User entered 'No (N)'	System	03 Nov 2020 05:05:12
	System	03 Nov 2020 05:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-03T00:05:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cbd2a3bd-35ae-4d2d-b122-b15b092e8fae' User entered '03 Nov 2020 00:05:08'	System	03 Nov 2020 05:05:12
	System	03 Nov 2020 05:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 71'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-12T08:32:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6e7b3574-d7e7-4d75-ad86-719bb0c05410'	System	12 Nov 2020 13:32:47
User entered 'No (N)'	System	12 Nov 2020 13:32:47

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-12T08:32:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6e7b3574-d7e7-4d75-ad86-719bb0c05410'	System	12 Nov 2020 13:32:47
User entered 'No (N)'	System	12 Nov 2020 13:32:47

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-12T08:32:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6e7b3574-d7e7-4d75-ad86-719bb0c05410' User entered '12 Nov 2020 08:32:43'	System	12 Nov 2020 13:32:47
	System	12 Nov 2020 13:32:47

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 78'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:45:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered 'Yes (Y)'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:45:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'No (N)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered 'Yes (Y)'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered 'No (N)'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '17 Nov 2020 11:46:43'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:56
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-23T12:19:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ec9b15b4-07a6-4f4b-afac-3a31242e1ac9' User entered 'No (N)'	System	23 Nov 2020 17:19:59
	System	23 Nov 2020 17:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-23T12:19:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ec9b15b4-07a6-4f4b-afac-3a31242e1ac9'	System	23 Nov 2020 17:19:59
User entered 'No (N)'	System	23 Nov 2020 17:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-23T12:19:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ec9b15b4-07a6-4f4b-afac-3a31242e1ac9' User entered '23 Nov 2020 12:19:54'	System	23 Nov 2020 17:19:59
	System	23 Nov 2020 17:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-28T00:01:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5170c361-16fa-4b69-858d-9a9a6ed9037b' User entered 'No (N)'	System	28 Nov 2020 05:02:46
	System	28 Nov 2020 05:02:46

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-28T00:02:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5170c361-16fa-4b69-858d-9a9a6ed9037b'	System	28 Nov 2020 05:02:46
User entered 'No (N)'	System	28 Nov 2020 05:02:46

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-28T00:02:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5170c361-16fa-4b69-858d-9a9a6ed9037b' User entered '28 Nov 2020 00:02:06'	System	28 Nov 2020 05:02:46
	System	28 Nov 2020 05:02:46

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-06T08:22:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '00d99ca7-ba7c-44d4-979c-59dffdf9088f' User entered 'Yes (Y)'	System	06 Dec 2020 13:22:41
	System	06 Dec 2020 13:22:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-06T08:22:14', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '00d99ca7-ba7c-44d4-979c-59dffdf9088f' User entered 'No (N)'	System	06 Dec 2020 13:22:41
	System	06 Dec 2020 13:22:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-06T08:22:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '00d99ca7-ba7c-44d4-979c-59dffdf9088f' User entered 'No (N)'	System	06 Dec 2020 13:22:41
	System	06 Dec 2020 13:22:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-06T08:22:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '00d99ca7-ba7c-44d4-979c-59dffdf9088f' User entered 'No (N)'	System	06 Dec 2020 13:22:41
	System	06 Dec 2020 13:22:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-06T08:22:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '00d99ca7-ba7c-44d4-979c-59dffdf9088f' User entered '06 Dec 2020 08:22:37'	System	06 Dec 2020 13:22:41
	System	06 Dec 2020 13:22:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-16T11:59:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '385ae96f-4201-45b1-ad77-116b6273d764' User entered 'No (N)'	System	16 Dec 2020 16:59:50
	System	16 Dec 2020 16:59:50

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-16T11:59:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '385ae96f-4201-45b1-ad77-116b6273d764' User entered 'No (N)'	System	16 Dec 2020 16:59:50
	System	16 Dec 2020 16:59:50

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-16T11:59:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '385ae96f-4201-45b1-ad77-116b6273d764' User entered '16 Dec 2020 11:59:48'	System	16 Dec 2020 16:59:50
	System	16 Dec 2020 16:59:50

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-19T07:30:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '34143601-1aae-4414-b871-bb53ff0bc5ff' User entered 'No (N)'	System	19 Dec 2020 12:30:38
	System	19 Dec 2020 12:30:38

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-19T07:30:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '34143601-1aae-4414-b871-bb53ff0bc5ff' User entered 'No (N)'	System	19 Dec 2020 12:30:38
	System	19 Dec 2020 12:30:38

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-19T07:30:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '34143601-1aae-4414-b871-bb53ff0bc5ff' User entered '19 Dec 2020 07:30:36'	System	19 Dec 2020 12:30:38
	System	19 Dec 2020 12:30:38

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-27T02:19:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e048e86f-eda8-4ebb-9365-b80ba6f76862'	System	27 Dec 2020 07:19:59
User entered 'No (N)'	System	27 Dec 2020 07:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-27T02:19:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e048e86f-eda8-4ebb-9365-b80ba6f76862'	System	27 Dec 2020 07:19:59
User entered 'No (N)'	System	27 Dec 2020 07:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-12-27T02:19:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e048e86f-eda8-4ebb-9365-b80ba6f76862' User entered '27 Dec 2020 02:19:57'	System	27 Dec 2020 07:19:59
	System	27 Dec 2020 07:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-02T00:01:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '97b18740-9184-4053-ac88-9d8e6d65ef38'	System	02 Jan 2021 05:01:53
User entered 'No (N)'	System	02 Jan 2021 05:01:53

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-02T00:01:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '97b18740-9184-4053-ac88-9d8e6d65ef38'	System	02 Jan 2021 05:01:53
User entered 'No (N)'	System	02 Jan 2021 05:01:53

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-02T00:01:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '97b18740-9184-4053-ac88-9d8e6d65ef38' User entered '02 Jan 2021 00:01:36'	System	02 Jan 2021 05:01:53
	System	02 Jan 2021 05:01:53

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-09T08:46:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1d212f5b-d029-496a-bd9b-fc7c9d9cc84e' User entered 'No (N)'	System	09 Jan 2021 13:46:27
	System	09 Jan 2021 13:46:27

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-09T08:46:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1d212f5b-d029-496a-bd9b-fc7c9d9cc84e' User entered 'No (N)'	System	09 Jan 2021 13:46:27

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-09T08:46:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1d212f5b-d029-496a-bd9b-fc7c9d9cc84e' User entered '09 Jan 2021 08:46:25'	System	09 Jan 2021 13:46:27
	System	09 Jan 2021 13:46:27

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-19T18:13:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '492e53d5-57dd-4b5e-88fb-2ae291f4380b' User entered 'No (N)'	System	19 Jan 2021 23:13:25
	System	19 Jan 2021 23:13:25

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-19T18:13:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '492e53d5-57dd-4b5e-88fb-2ae291f4380b' User entered 'No (N)'	System	19 Jan 2021 23:13:25

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-19T18:13:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '492e53d5-57dd-4b5e-88fb-2ae291f4380b' User entered '19 Jan 2021 18:13:23'	System	19 Jan 2021 23:13:25
	System	19 Jan 2021 23:13:25

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-25T12:00:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c5c29b4d-20d0-42e8-9167-a84caefde1bc' User entered 'No (N)'	System	25 Jan 2021 17:00:40
	System	25 Jan 2021 17:00:40

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-25T12:00:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c5c29b4d-20d0-42e8-9167-a84caefde1bc'	System	25 Jan 2021 17:00:40
User entered 'No (N)'	System	25 Jan 2021 17:00:40

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-25T12:00:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c5c29b4d-20d0-42e8-9167-a84caefde1bc' User entered '25 Jan 2021 12:00:20'	System	25 Jan 2021 17:00:40
	System	25 Jan 2021 17:00:40

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-30T08:42:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '979ea1a3-6f02-4f24-92a7-aff107c07ff5'	System	30 Jan 2021 13:43:20
User entered 'No (N)'	System	30 Jan 2021 13:43:20

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-30T08:42:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '979ea1a3-6f02-4f24-92a7-aff107c07ff5'	System	30 Jan 2021 13:43:20
User entered 'No (N)'	System	30 Jan 2021 13:43:20

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-01-30T08:43:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '979ea1a3-6f02-4f24-92a7-aff107c07ff5' User entered '30 Jan 2021 08:43:17'	System	30 Jan 2021 13:43:20

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-06T07:22:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '17b772f1-107a-400c-8ca5-925fe89f174b' User entered 'No (N)'	System	06 Feb 2021 12:22:49
	System	06 Feb 2021 12:22:49

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-06T07:22:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '17b772f1-107a-400c-8ca5-925fe89f174b' User entered 'No (N)'	System	06 Feb 2021 12:22:49
	System	06 Feb 2021 12:22:49

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-06T07:22:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '17b772f1-107a-400c-8ca5-925fe89f174b' User entered '06 Feb 2021 07:22:47'	System	06 Feb 2021 12:22:49
	System	06 Feb 2021 12:22:49

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-13T01:11:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0bd495ae-82a8-47e7-9c8b-47bee4466a6e' User entered 'No (N)'	System	18 Feb 2021 16:03:40
	System	18 Feb 2021 16:03:40

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-13T01:11:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0bd495ae-82a8-47e7-9c8b-47bee4466a6e' User entered 'No (N)'	System	18 Feb 2021 16:03:40
	System	18 Feb 2021 16:03:40

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-13T01:11:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0bd495ae-82a8-47e7-9c8b-47bee4466a6e' User entered '13 Feb 2021 01:11:57'	System	18 Feb 2021 16:03:40
	System	18 Feb 2021 16:03:40

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-21T12:29:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ad82142e-692c-4bd0-ac12-8e3a70c59d28' User entered 'No (N)'	System	21 Feb 2021 17:29:43
	System	21 Feb 2021 17:29:43

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-21T12:29:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ad82142e-692c-4bd0-ac12-8e3a70c59d28' User entered 'No (N)'	System	21 Feb 2021 17:29:43

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-21T12:29:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ad82142e-692c-4bd0-ac12-8e3a70c59d28' User entered '21 Feb 2021 12:29:39'	System	21 Feb 2021 17:29:43

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-27T07:45:34-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '7877cc7f-c023-4be1-9d8a-ae3d816983d2' User entered 'No (N)'	System	27 Feb 2021 12:45:45

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-27T07:45:38-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '7877cc7f-c023-4be1-9d8a-ae3d816983d2'	System	27 Feb 2021 12:45:45
User entered 'No (N)'	System	27 Feb 2021 12:45:45

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-02-27T07:45:42-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '7877cc7f-c023-4be1-9d8a-ae3d816983d2' User entered '27 Feb 2021 12:45:42'	System	27 Feb 2021 12:45:45
	System	27 Feb 2021 12:45:45

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-06T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f577ee17-b287-4218-80e4-addb2af772b3'	System	06 Mar 2021 05:04:52
User entered 'No (N)'	System	06 Mar 2021 05:04:52

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-06T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f577ee17-b287-4218-80e4-addb2af772b3'	System	06 Mar 2021 05:04:52
User entered 'No (N)'	System	06 Mar 2021 05:04:52

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-06T00:02:43-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f577ee17-b287-4218-80e4-addb2af772b3' User entered '06 Mar 2021 00:02:43'	System	06 Mar 2021 05:04:52
	System	06 Mar 2021 05:04:52

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-13T00:09:58-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8f66cb7-1f43-4253-819a-20445e87f17b'	System	18 Mar 2021 20:29:04
User entered 'No (N)'	System	18 Mar 2021 20:29:04

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-13T00:10:05-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8f66cb7-1f43-4253-819a-20445e87f17b'	System	18 Mar 2021 20:29:04
User entered 'No (N)'	System	18 Mar 2021 20:29:04

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-13T00:10:09-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8f66cb7-1f43-4253-819a-20445e87f17b'	System	18 Mar 2021 20:29:04
User entered '13 Mar 2021 00:10:09'	System	18 Mar 2021 20:29:04

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-23T17:59:20-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f24baafe-ef6c-481a-98a7-7ca524f9b3db'	System	23 Mar 2021 21:59:41
User entered 'No (N)'	System	23 Mar 2021 21:59:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-23T17:59:27-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f24baafe-ef6c-481a-98a7-7ca524f9b3db'	System	23 Mar 2021 21:59:41
User entered 'No (N)'	System	23 Mar 2021 21:59:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-23T17:59:31-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f24baafe-ef6c-481a-98a7-7ca524f9b3db' User entered '23 Mar 2021 17:59:31'	System	23 Mar 2021 21:59:41

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-28T08:38:49-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2ebf2acb-4f82-4b64-9004-cf6545f5b38e' User entered 'No (N)'	System	01 Apr 2021 16:37:08
	System	01 Apr 2021 16:37:08

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-28T08:38:52-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2ebf2acb-4f82-4b64-9004-cf6545f5b38e' User entered 'No (N)'	System	01 Apr 2021 16:37:08
	System	01 Apr 2021 16:37:08

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-28T08:39:00-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2ebf2acb-4f82-4b64-9004-cf6545f5b38e' User entered '28 Mar 2021 08:39:00'	System	01 Apr 2021 16:37:08
	System	01 Apr 2021 16:37:08

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-03T00:02:27-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '896503f8-669b-4106-b47b-981e084fa818'	System	03 Apr 2021 04:03:47
User entered 'No (N)'	System	03 Apr 2021 04:03:47

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-03T00:02:30-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '896503f8-669b-4106-b47b-981e084fa818'	System	03 Apr 2021 04:03:47
User entered 'No (N)'	System	03 Apr 2021 04:03:47

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-03T00:02:35-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '896503f8-669b-4106-b47b-981e084fa818'	System	03 Apr 2021 04:03:47
User entered '03 Apr 2021 00:02:35'	System	03 Apr 2021 04:03:47

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-10T00:02:52-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1883ec5a-f793-4996-abaf-389b72723f5c'	System	10 Apr 2021 04:06:04
User entered 'No (N)'	System	10 Apr 2021 04:06:04

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-10T00:02:54-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1883ec5a-f793-4996-abaf-389b72723f5c'	System	10 Apr 2021 04:06:04
User entered 'No (N)'	System	10 Apr 2021 04:06:04

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-10T00:02:58-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1883ec5a-f793-4996-abaf-389b72723f5c'	System	10 Apr 2021 04:06:04
User entered '10 Apr 2021 00:02:58'	System	10 Apr 2021 04:06:04

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-17T00:08:26-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1b6e4d92-3e9c-491c-bf14-a02110d714a4'	System	24 Apr 2021 18:42:22
User entered 'No (N)'	System	24 Apr 2021 18:42:22

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-17T00:08:30-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1b6e4d92-3e9c-491c-bf14-a02110d714a4'	System	24 Apr 2021 18:42:22
User entered 'No (N)'	System	24 Apr 2021 18:42:22

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-17T00:08:34-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1b6e4d92-3e9c-491c-bf14-a02110d714a4'	System	24 Apr 2021 18:42:22
User entered '17 Apr 2021 00:08:34'	System	24 Apr 2021 18:42:22

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-24T14:42:23-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '23024d47-27b0-4fbe-b31c-8269cce46f45'	System	24 Apr 2021 18:42:30
User entered 'No (N)'	System	24 Apr 2021 18:42:30

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-24T14:42:25-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '23024d47-27b0-4fbe-b31c-8269cce46f45'	System	24 Apr 2021 18:42:30
User entered 'No (N)'	System	24 Apr 2021 18:42:30

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-04-24T14:42:28-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '23024d47-27b0-4fbe-b31c-8269cce46f45'	System	24 Apr 2021 18:42:30
User entered '24 Apr 2021 14:42:28'	System	24 Apr 2021 18:42:30

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-05-02T08:44:14-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '080c0de2-1848-49f3-a4c5-2bab1d16ef5a'	System	02 May 2021 12:44:23
User entered 'No (N)'	System	02 May 2021 12:44:23

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-05-02T08:44:16-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '080c0de2-1848-49f3-a4c5-2bab1d16ef5a'	System	02 May 2021 12:44:23
User entered 'No (N)'	System	02 May 2021 12:44:23

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-05-02T08:44:19-04:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '080c0de2-1848-49f3-a4c5-2bab1d16ef5a'	System	02 May 2021 12:44:23
User entered '02 May 2021 08:44:19'	System	02 May 2021 12:44:23

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:24:59

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 18:35:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-06T00:03:00-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3ce555fe-2121-4bae-8af6-9cf28c3f8f80'	System	13 Mar 2021 05:10:32
User entered 'Yes (Y)'	System	13 Mar 2021 05:10:32

US3762177

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:24:59

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:35:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-06T00:03:05-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3ce555fe-2121-4bae-8af6-9cf28c3f8f80'	System	13 Mar 2021 05:10:32
User entered 'No (N)'	System	13 Mar 2021 05:10:32

US3762177

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:24:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:35:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2021-03-06T00:03:31-05:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3ce555fe-2121-4bae-8af6-9cf28c3f8f80' User entered '06 Mar 2021 00:03:31'	System	13 Mar 2021 05:10:32
	System	13 Mar 2021 05:10:32

US3762177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:55:28

US3762177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:11
User entered '04 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:55:28

US3762177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:55:28

US3762177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:11
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:55:28

US3762177

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:55:32

US3762177

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:58:53
User entered 'I'	System	04 Dec 2020 18:55:32

US3762177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Dec 2020 21:09:50

US3762177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '30 Dec 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Dec 2020 21:09:50

US3762177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Dec 2020 21:09:50

US3762177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Dec 2020 21:09:50

US3762177

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Dec 2020 21:09:54

US3762177

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User entered 'I'	System	30 Dec 2020 21:09:54

US3762177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 20:12:44

US3762177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 20:12:44

US3762177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 20:12:44

US3762177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 20:12:44

US3762177

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 20:12:49

US3762177

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User entered 'I'	System	25 Feb 2021 20:12:49

US3762177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	26 Feb 2021 17:19:55

US3762177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '26 Feb 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	26 Feb 2021 17:19:55

US3762177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	26 Feb 2021 17:19:55

US3762177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	26 Feb 2021 17:19:55

US3762177

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	26 Feb 2021 17:20:01

US3762177

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:26:04
User entered 'I'	System	26 Feb 2021 17:20:01

US3762177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:49

US3762177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:49

US3762177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[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 18:37:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:49

US3762177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 16:43:49

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 16:43:58

US3762177

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:44:04

US3762177

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:44:04

US3762177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:07:39

US3762177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:07:39

US3762177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '12:46'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:07:39

US3762177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 12:46'	System	01 Apr 2021 17:07:39

US3762177

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:44:19

US3762177

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 16:44:19

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:24:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:31:15

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:24:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered '10:00'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:31:15

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:24:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:51
User entered '18 Sep 2020 10:00'	System	13 Oct 2020 15:31:15

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:24:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:31:15

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:24:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:31:15

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Day 1 (Day 1)'	(b) (4) Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '19 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '100'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User entered '%'	System	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '97.7' F	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:24:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:33:11

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Day 2 (Day 2)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '20 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '100'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User entered '%'	System	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '96.5' F	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:24:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:34:20

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Day 3 (Day 3)'	(b) (4) Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '21 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User entered '%'	System	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:24:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:35:12

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per GCL Lab Recon: GCL has SARS-CoV-2 sample with date of 18SEP2020; however Illness Visit is not completed. Please reconcile or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:51:33
Query 'Per GCL Lab Recon: GCL has SARS-CoV-2 sample with date of 18SEP2020; however Illness Visit is not completed. Please reconcile or clarify. ' answered with 'unscheduled visit ' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 15:35:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User opened query 'Per GCL Lab Recon: GCL has SARS-CoV-2 sample with date of 18SEP2020; however Illness Visit is not completed. Please reconcile or clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:03:04
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'No (N)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'No (N)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:24:59

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:59
User entered '0'	System	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:24:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:55:03
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:37:03

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 20Sep2020 is reported under Illness Visit Day 3 in EDC, however same is reported for Day 7 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 07:22:01
Query 'Per GCL Lab Recon: Saliva: Sample dated 20Sep2020 is reported under Illness Visit Day 3 in EDC, however same is reported for Day 7 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' answered with 'Day 3 is the correct visit. Site has submitted a Demographic change request form to PPD ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:58:45
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 20Sep2020 is reported under Illness Visit Day 3 in EDC, however same is reported for Day 7 in PPD central lab. Please confirm the correct visit in query response and update the visit mismatch in EDC or Preclarus as appropriate, Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:36:07
User entered '20 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:24:59

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:24:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:22
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:22
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '18 Sep 2020'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:22
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Clinic (Clinic)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:22
User entered 'SICKD1'	System	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '18 Sep 2020'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '10:00'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User entered '18 Sep 2020 10:00'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	19 Nov 2020 20:03:46
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	19 Nov 2020 20:03:46
User entered '63' in reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:46
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	
User entered '145' in	System	19 Nov 2020 20:03:28
DataPoint set to visible.	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	
	System	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4)	19 Nov 2020 20:03:46
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	19 Nov 2020 20:03:46
User entered '145' lb reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:46
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	(b) (4)	
User entered '63' lb	System	19 Nov 2020 20:03:28
DataPoint set to visible.	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	
	System	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '97.8' F	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Oral (Oral)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '70'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User entered 'bpm'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '16'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User entered 'breaths/min'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '125'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User entered 'mmHg'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '68'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27
User entered 'mmHg'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:27

US3762177

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:30
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:04:02

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:30
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '18 Sep 2020'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:04:02

US3762177

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:24:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:04:18

US3762177

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:24:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:32:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '18 Sep 2020'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:04:18

US3762177

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

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:24

US3762177

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

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:24

US3762177

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

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:24

US3762177

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

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 17:14:24

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:32:08

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:32:08

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	27 Jan 2021 17:14:54

US3762177

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

Form: Unblinding

Generated On: 12 Aug 2021 13:24:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'I'	System	27 Jan 2021 17:14:54

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	27 Jan 2021 17:16:36
DataPoint set to visible.	System	27 Jan 2021 17:14:54

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	27 Jan 2021 17:16:36
DataPoint set to visible.	System	27 Jan 2021 17:14:54

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '10:37'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '27 Jan 2021 10:37'	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	27 Jan 2021 17:16:52
User entered '98.0' F reason for change: Data Entry Error	System	27 Jan 2021 17:16:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	27 Jan 2021 17:16:36
User entered '98.0' (non-conformant).	System	27 Jan 2021 17:16:36
	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '68'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'bpm'	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '15'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'breaths/min'	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '111'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mmHg'	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '74'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mmHg'	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered empty.	System	27 Jan 2021 17:16:36
DataPoint set to visible.	System	27 Jan 2021 17:14:54

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Jan 2021 17:32:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Jan 2021 17:32:36
User entered '12:26' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Jan 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '27 Jan 2021 12:26'	System	27 Jan 2021 17:32:36
User entered empty.	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Jan 2021 17:32:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Jan 2021 17:32:36
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Jan 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	27 Jan 2021 17:32:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Jan 2021 17:32:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Jan 2021 17:32:36
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Jan 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'bpm'	System	27 Jan 2021 17:32:36
User entered empty.	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Jan 2021 17:32:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Jan 2021 17:32:36
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Jan 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'breaths/min'	System	27 Jan 2021 17:32:36
User entered empty.	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Jan 2021 17:32:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Jan 2021 17:32:36
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Jan 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mmHg'	System	27 Jan 2021 17:32:36
User entered empty.	System	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Jan 2021 17:32:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	27 Jan 2021 17:32:36
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 17:32:36
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Jan 2021 17:16:36
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 17:16:36

US3762177

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mmHg'	System	27 Jan 2021 17:32:36
User entered empty.	System	27 Jan 2021 17:16:36

US3762177

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:17:21

US3762177

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:17:21

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mRNA-1273'	System	27 Jan 2021 17:18:09
DataPoint set to visible.	System	27 Jan 2021 17:14:54

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '11:56'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '27 Jan 2021 11:56'	System	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'ONCE'	System	27 Jan 2021 17:18:09

US3762177

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

Form: Exposure

Generated On: 12 Aug 2021 13:24:59

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 17:18:09

US3762177

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:19:44

US3762177

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:19:44

US3762177

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '10:40'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:19:44

US3762177

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '27 Jan 2021 10:40'	System	27 Jan 2021 17:19:44

US3762177

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:20:07

US3762177

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:24:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:20:07

US3762177

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:24:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '10:43'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:20:07

US3762177

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:24:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '27 Jan 2021 10:43'	System	27 Jan 2021 17:20:07

US3762177

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

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:20:14

US3762177

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

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'I'	System	27 Jan 2021 17:20:14

US3762177

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:12:52

US3762177

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:12:52

US3762177

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:12:52

US3762177

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:12:52

US3762177

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:13:00

US3762177

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User entered 'I'	System	03 Feb 2021 14:13:00

US3762177

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:59

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:41
User entered 'I'	System	03 Feb 2021 14:13:00
DataPoint set to visible.	System	03 Feb 2021 14:13:00

US3762177

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:03

US3762177

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:03

US3762177

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:03

US3762177

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'OLD29'	System	24 Feb 2021 14:55:03

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '09:31'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '24 Feb 2021 09:31'	System	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '67'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'bpm'	System	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'breaths/min'	System	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '106'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

US3762177

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mmHg'	System	24 Feb 2021 14:55:42

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '69'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:55:42

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered 'mmHg'	System	24 Feb 2021 14:55:42

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:36:26

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:36:26

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:56:13

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per response, "Per source patient has yet to have an OL V3."; however, per PPD portal, 24-FEB-2021 immuno sample is present under OL-3 visit & in EDC it is captured under OL-2. Kindly review & confirm if 24-FEB-2021 sample belongs to OL-2 visit, to be updated in PPD portal as appropriate, else clarify the correct visit name.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:44:47
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per response, "Per source patient has yet to have an OL V3."; however, per PPD portal, 24-FEB-2021 immuno sample is present under OL-3 visit & in EDC it is captured under OL-2. Kindly review & confirm if 24-FEB-2021 sample belongs to OL-2 visit, to be updated in PPD portal as appropriate, else clarify the correct visit name.' answered with '24Feb21 sample belongs to OL-2 visit. Site has submitted a demographic change request form. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:51:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per response, "Per source patient has yet to have an OL V3."; however, per PPD portal, 24-FEB-2021 immuno sample is present under OL-3 visit & in EDC it is captured under OL-2. Kindly review & confirm if 24-FEB-2021 sample belongs to OL-2 visit, to be updated in PPD portal as appropriate, else clarify the correct visit name.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:04:32
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per response, "Per source patient has yet to have an OL V3."; however, per PPD portal, 24-FEB-2021 immuno sample is present under OL-3 visit & in EDC it is captured under OL-2. Kindly review & confirm if 24-FEB-2021 sample belongs to OL-2 visit, to be updated in PPD portal as appropriate, else clarify the correct visit name.' canceled (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:04:28

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EAB) (1725)

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per response, "Per source patient has yet to have an OL V3."; however, per PPD portal, 24-FEB-2021 immuno sample is present under OL-3 visit & in EDC it is captured under OL-2. Kindly review & confirm if 24-FEB-2021 sample belongs to OL-2 visit, to be updated in PPD portal as appropriate, else clarify the correct visit name.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:04:24
User closed query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 24 FEB 2021 is recorded under the OL-D29 visit in EDC, however the same is reported under in OL-3 visit PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:04:32
Query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 24 FEB 2021 is recorded under the OL-D29 visit in EDC, however the same is reported under in OL-3 visit PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Per source patient has yet to have an OL V3.' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	03 Mar 2021 18:07:10
User opened query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 24 FEB 2021 is recorded under the OL-D29 visit in EDC, however the same is reported under in OL-3 visit PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:59:40
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 14:56:13

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '09:34'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:56:13

US3762177

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:32:21
User entered '24 Feb 2021 09:34'	System	24 Feb 2021 14:56:13

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:24:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:28:15
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:28
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 1; end date: Day 37). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 13:41:33
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 1; end date: Day 37). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'AE log updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:17:45
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 1; end date: Day 37). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 09:25:32
User closed query 'Per CDM: refer to log line 1, 2, 3, and 4. Action taken is recorded as IP withdrawal for log line 1,2,3 and 4. This action taken should only be selected for 1 event-the primary reason for discontinuation of IP. Please update. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 06:43:18
Query 'Per CDM: refer to log line 1, 2, 3, and 4. Action taken is recorded as IP withdrawal for log line 1,2,3 and 4. This action taken should only be selected for 1 event-the primary reason for discontinuation of IP. Please update. ' answered with 'updated to reflect only log line 1 to be the reason of IP discontinuation' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	25 Nov 2020 18:30:05

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:24:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: refer to log line 1, 2, 3, and 4. Action taken is recorded as IP withdrawal for log line 1,2,3 and 4. This action taken should only be selected for 1 event-the primary reason for discontinuation of IP. Please update. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:47:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:28:52
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:09:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:27:31
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 06:30:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 06:30:46
Data point term sent to Coder	System	10 Nov 2020 18:59:37
Query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	10 Nov 2020 18:59:35
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 18:59:29
Coding entries removed.	Samantha Wheeler (b) (4)	10 Nov 2020 18:59:29
User entered 'INJECTION SITE REDNESS, LEFT ARM non-urticarial' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 18:59:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:13:02
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:13:40
Data point term sent to Coder	System	21 Sep 2020 14:12:27
User entered 'INJECTION SITE REDNESS, LEFT ARM'	James Lovette (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '03 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '00:00'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User entered '03 Sep 2020 00:00'	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per CDM: Response noted.However ,please update the field specified Ongoing=No and If not Ongoing End Date = 09/21/20.Please update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 18:29:21
Query 'Per CDM: Response noted.However ,please update the field specified Ongoing=No and If not Ongoing End Date = 09/21/20.Please update eCRF as appropriate' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:30
DataPoint Un-verified.	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:18
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:18
User opened query 'Per CDM: Response noted.However ,please update the field specified Ongoing=No and If not Ongoing End Date = 09/21/20.Please update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 14:52:16
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. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 14:48:57
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. ' answered with 'RESOLVED 09/21/2020' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:49:38
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. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 02:37:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User entered '9 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 17:17:10
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	17 Dec 2020 16:20:43
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	17 Dec 2020 16:20:43
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	17 Dec 2020 16:20:18
DataPoint Un-verified.	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:18
	(b) (4)	
User entered '04 Sep 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 16:20:43
DataPoint Un-verified.	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:43
	(b) (4)	
User entered '00:00' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:43
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Dec 2020 16:20:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User entered '9 Oct 2020 00:00'	System	25 Feb 2021 17:17:10
User entered '04 Sep 2020 00:00'	System	17 Dec 2020 16:20:43
User entered empty.	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 10:21:43
Query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'this began after first dose of IP' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	10 Nov 2020 19:00:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:53:44
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:06
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:41
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Generated On: 12 Aug 2021 13:24:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'I'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:43
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Samantha Wheeler (b) (4)	17 Dec 2020 16:20:43
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User entered '0'	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47
User entered '0'	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User closed query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria (i.e., eDiary Fatigue Day 8 = NO Information). Please review and confirm if Fatigue is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:33:31
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
Query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria (i.e., eDiary Fatigue Day 8 = NO Information). Please review and confirm if Fatigue is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' answered with 'patient was put into an illness visit and reported fatigue on telemedicine calls' (Site from DM).	(b) (4) Samantha Wheeler (b) (4)	09 Apr 2021 16:32:10
User opened query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if this meets AE reporting criteria per protocol section 8.3.4. Please review if recorded event meets criteria (i.e., eDiary Fatigue Day 8 = NO Information). Please review and confirm if Fatigue is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:26:06
User closed query 'Per MM, Please confirm if subject received second dose of IP' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 23:34:56
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 23:34:54

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' answered with 'patient did come in for illness visit' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:39:51
Query 'Per MM, Please confirm if subject received second dose of IP' answered with 'subject did not receive second dose of IP' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:39:41
User opened query 'Per MM, Please confirm if subject received second dose of IP' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:51:19
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:50:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:15:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:15:51
Data point term sent to Coder	System	21 Sep 2020 14:14:32
User entered 'FATIGUE'	James Lovette (b) (4)	21 Sep 2020 14:14:01

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '04 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

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Generated On: 12 Aug 2021 13:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '00:00'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User entered '04 Sep 2020 00:00'	System	21 Sep 2020 14:14:01

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:08:04
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'status updated per AE log ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:56:03
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:55:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:55:30
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:21:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:14:01

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
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	25 Jan 2021 17:55:45
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	25 Jan 2021 17:55:45
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	25 Jan 2021 17:55:30
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:55:30
User entered '20 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:55:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Jan 2021 17:56:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:56:16
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:56:16
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Jan 2021 17:55:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User entered '20 Sep 2020 00:00'	System	25 Jan 2021 17:56:16
User entered empty.	System	21 Sep 2020 14:14:01

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
	(b) (4)	
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	25 Nov 2020 18:29:22
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	25 Nov 2020 18:29:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:29
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:52
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
	(b) (4)	
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:55:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	25 Jan 2021 17:55:45
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User entered '0'	System	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48
User entered '0'	System	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:48

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #6. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:08:16
Query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #6. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' answered with 'Dates do not overlap per pt report ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:57:44
User opened query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #6. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:26:44
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach ache - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 14:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 14:16:43
Data point term sent to Coder	System	21 Sep 2020 14:15:34
User entered 'STOMACH ACHE'	James Lovette (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, stomach ache is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:13:13
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, stomach ache is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:40:13
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	24 Oct 2020 23:40:06
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, stomach ache is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:47:50
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '13 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User entered empty.	System	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
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) (6)	14 Dec 2020 14:52:46
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 'PER PATIENT RESOLVED ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:03:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:02:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 15:02:51
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 02:37:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:02:51
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 15:02:51
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User entered empty.	System	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
	(b) (4)	
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	25 Nov 2020 18:29:33
	(b) (4)	
User entered 'None (NONE)' reason for change:	Samantha Wheeler (b) (4)	25 Nov 2020 18:29:33
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:54
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:12
	(b) (4)	
User entered 'Investigational Product Withdrawn	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:12
(WITHDRAWN)' reason for change: Data Entry	(b) (4)	
Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
	(b) (4)	
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:24:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 18:29:44
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 15:20:59
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 15:20:48
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 15:20:48
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 21:11:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 15:20:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 15:20:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 15:02:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	04 Dec 2020 15:02:51
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User entered '0'	System	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51
User entered '0'	System	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:51

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Folder: Adverse Events

Form: Adverse Events (4)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:18:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:18:39
	(b) (4)	
Data point term sent to Coder	System	21 Sep 2020 14:17:35
User entered 'INTERMITTENT BODY ACHES'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Body Aches is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update AE term to record the actual solicited event term.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:24:36
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Body Aches is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update AE term to record the actual solicited event term.' answered with 'updated per query' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:50:51
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	24 Oct 2020 23:50:45
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Body Aches is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update AE term to record the actual solicited event term.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:47:31
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:16:35

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

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Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '04 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 14:16:50
User entered '00:00' reason for change: Data Entry Error	James Lovette (b) (4)	21 Sep 2020 14:16:50
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 14:16:35
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User entered '04 Sep 2020 00:00'	System	21 Sep 2020 14:16:50
User entered empty.	System	21 Sep 2020 14:16:35

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 16:24:25
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:58:27
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:58:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:58:20
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:25:27
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:16:35

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:58:20
User entered '4 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:58:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Jan 2021 17:58:35
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:58:35
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:58:35
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Jan 2021 17:58:20
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User entered '4 Nov 2020 00:00'	System	25 Jan 2021 17:58:35
User entered empty.	System	21 Sep 2020 14:16:35

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Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
	(b) (4)	
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	25 Nov 2020 18:29:45
	(b) (4)	
User entered 'None (NONE)' reason for change:	Samantha Wheeler (b) (4)	25 Nov 2020 18:29:45
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:14
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:28
	(b) (4)	
User entered 'Investigational Product Withdrawn	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:28
(WITHDRAWN)' reason for change: Data Entry	(b) (4)	
Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
	(b) (4)	
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 19:35:13
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 22:38:51
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 22:38:43
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 22:38:43
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 21:10:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 22:38:43
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 22:38:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:58:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	25 Jan 2021 17:58:20
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User entered '0'	System	21 Sep 2020 14:16:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53
User entered '0'	System	21 Sep 2020 14:16:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:53

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 05:50:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 05:50:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
Data point term sent to Coder	System	05 Nov 2020 18:11:49
User entered 'Vomit'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User entered empty.	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User entered empty.	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:01:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:01:54
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:11:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:01:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:01:54
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:11:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Pt stated she ate leftovers on 10/26/2020 and had vomiting on 10/27/2020 and stomach pain from 10/27/2020 until Visit 3 with her PCP on 11/2/2020. PCP prescribed Ventyl PRN for stomach pains and pt took her first dose 11/3/2020. PCP indicated to the pt that this may be more related to her IBS and diverticulitis than cove study.'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User entered '0'	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57
User entered '0'	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:57

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:13:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:13:21
Data point term sent to Coder	System	05 Nov 2020 18:12:52
User entered 'Stomach pains'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:02:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:02:26
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:12:15
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:02:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:02:26
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:12:15
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:08:57
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Same as stomach pain ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 15:23:17
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 21:13:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Pt stated she ate leftovers on 10/26/2020 and had vomiting on 10/27/2020 and stomach pain from 10/27/2020 until Visit 3 with her PCP on 11/2/2020. PCP prescribed Ventyl PRN for stomach pains and pt took her first dose 11/3/2020. PCP indicated to the pt that this may be more related to her IBS and diverticulitis than cove study.'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:24:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 18:12:15

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:28:15
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 11:21:08
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'will enter' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	09 Apr 2021 16:11:26
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:59:24
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:27:02

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:29:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:29:42
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 11:28:48
User entered 'Levothyroxine'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:31:59
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'update' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:28:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Hypothyroid'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '125'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'ug (ug)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:08
User entered 'Other (OTHER)'	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	19 Oct 2020 11:38:59
' (Site from DM).		
Query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:26
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:08
	(b) (4)	
User opened query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	18 Sep 2020 05:42:52
' (Site from DM).		
User entered 'mcg'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '01 Sep 1983'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 11:30:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 11:30:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:30:05
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 11:28:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:30:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:30:43
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 11:29:48
User entered 'Liothyronine'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:27:22
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:26:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:28:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Hypothyroid'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '10'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'ug (ug)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:26:31
User entered 'Other (OTHER)'	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	19 Oct 2020 11:39:16
' (Site from DM).		
Query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	Samantha Wheeler (b) (4)	13 Oct 2020 15:26:45
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:26:31
	(b) (4)	
User opened query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	18 Sep 2020 05:43:23
' (Site from DM).		
User entered 'mcg'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 May 2020'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:32:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:32:43
Data point term sent to Coder	System	11 Sep 2020 11:31:49
User entered 'Wellbutrin'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:27:47
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:29:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'depression'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '150'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Unknown'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '01 UNK 2000'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Sep 2020 11:34:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Sep 2020 11:34:44
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 11:33:50
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:26:03
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:41
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:29:53
User entered 'muscle aches'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '325'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:36
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User entered '1'	System	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User entered '1'	System	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:33
User entered '804 (804)'	System	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Sep 2020 11:36:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Sep 2020 11:36:45
Data point term sent to Coder	System	11 Sep 2020 11:35:53
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:32:32
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:26
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:30:05
User entered 'muscle aches'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '325'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '07 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '07 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:21
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User entered '1'	System	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User entered '1'	System	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:37
User entered '804 (804)'	System	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
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)	10 Nov 2020 19:05:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:05:53
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	10 Nov 2020 19:04:52 10 Nov 2020 19:04:02
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)	21 Sep 2020 14:05:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:05:51
Data point term sent to Coder User entered 'acetaminophen'	System James Lovette (b) (4)	21 Sep 2020 14:04:10 21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe (05-07SEP2020). If the INTERMITTENT BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INTERMITTENT BODY ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:18:48
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe (05-07SEP2020). If the INTERMITTENT BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INTERMITTENT BODY ACHES did not meet the AE reporting criteria.' answered with 'Solicited adverse reaction' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 18:35:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe (05-07SEP2020). If the INTERMITTENT BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INTERMITTENT BODY ACHES did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 16:08:07
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
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 MUSCLE ACHES 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 MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:37:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES 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 MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'updated to match AE for body aches' (Site from DM).	Samantha Wheeler (b) (4)	10 Nov 2020 19:04:12
User entered 'intermittent body aches' reason for change: Data Entry Error	(b) (4)	
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 MUSCLE ACHES 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 MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:02:23
User entered 'muscle aches'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of capsule count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:29:30
Query 'Per DM CLR: Please provide the actual dose for this medication instead of capsule count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 20:20:24
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 20:20:09
User entered '250' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:20:09
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of capsule count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:55:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '1'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 20:20:09
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 20:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'capsule (CAPSULE)'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'as needed (PRN)'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '07 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:54:17
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated to yes' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 18:41:23
DataPoint Un-verified.	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 18:35:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 18:35:34
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 16:03:20
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User entered empty.	System	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User entered empty.	System	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:43
User entered empty.	System	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:14:14
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:14:14
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 15:24:37
User entered 'omeprazole'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'stomach ache'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '20'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'as needed (PRN)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '13 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:10:40
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:14
DataPoint Un-verified.	(b) (4)	22 Feb 2021 20:52:40
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 20:52:40
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:44:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Feb 2021 20:52:45
User entered '14 Sep 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 20:52:45
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Feb 2021 20:52:40
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 20:52:40
	(b) (4)	
User entered '14 Sep 2021' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 20:52:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:10:44
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 20:40:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 20:40:29
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4)	22 Feb 2021 20:40:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 00:44:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:31:48
	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User entered empty.	System	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User entered empty.	System	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:48
User entered empty.	System	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:05:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 16:05:20
Data point term sent to Coder	System	13 Oct 2020 15:25:38
User entered 'immodium'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'stomach ache'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '2'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'as needed (PRN)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '13 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:11:11
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:47
DataPoint Un-verified.	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 00:44:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:31:48
	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:43
	(b) (4)	
User entered '14 Sep 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:11:13
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 20:53:43
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' canceled (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 20:53:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:44:37
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 00:44:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 00:44:22
	(b) (4), (b) (6)	19 Nov 2020 17:31:48
	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User entered empty.	System	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User entered empty.	System	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:52
User entered empty.	System	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med BENTYL was added/changed on 13 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 10:33:57
Query 'Per DM CLR: Con Med BENTYL was added/changed on 13 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no worsening reported' (Site from DM).	John Sanders (b) (4) (b) (4) Samantha Wheeler (b) (4) (b) (4)	12 Apr 2021 18:37:34 09 Apr 2021 16:33:27
User opened query 'Per DM CLR: Con Med BENTYL was added/changed on 13 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:45:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE HYDROCHLORIDE, PRODUCTSYNONYM: BENTYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:14:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:14:58
Data point term sent to Coder	System	04 Dec 2020 15:14:01
User entered 'BENTYL'	(b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:01:49
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'corrected' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:54:16
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:54:10
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:57:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'IBS'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:01:57
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'corrected' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:54:20
User entered '10' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:54:10
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:57:43
User entered '10MG'	(b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:24:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:13:33

US3762177

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:24:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:28:52

US3762177

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:24:59

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:17:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered '03 Sep 2020'	(b) (4) Samantha Wheeler (b) (4)	25 Nov 2020 18:52:29

US3762177

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:24:59

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:17:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	25 Nov 2020 18:52:29

US3762177

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:24:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:17:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:34
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:44:25
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	08 Apr 2021 22:37:56
User entered 'INJECTION SITE REACTION AE1, AE2, AE3, and AE4' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	08 Apr 2021 22:37:52
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:20:14
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:19:49
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:19:36
User entered 'injection site reaction'	Samantha Wheeler (b) (4) (b) (4)	25 Nov 2020 18:52:29