

US3812257 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:37:16

All time stamps listed in this document are displayed in GMT

US3812257

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 23:39:16

Generated On: 12 Aug 2021 13:37:16

[Participant ID](#)

US3812257

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

US3812257

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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

Visit date (dd MMM yyyy)	25 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3812257

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 23:39:38

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Date of Informed Consent (<i>dd MMM yyyy</i>)	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 23:39:38

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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) 20 Feb 2021 23:39:39

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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) 20 Feb 2021 23:39:39

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Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN AUG 2012
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 AUG 2012
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2012
Start Year (derived)	2012
Stop Month and Year (derived)	AUG 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	LEFT CARPEL TUNNEL REPAIR
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	LIPID MICROSPHERE ALLERGY
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	COCONUT ALLERGY
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	LEFT CARPEL TUNNEL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	UN DEC 2018
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 DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3812257

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	POTASSIUM DEFICIENCY
Start date (dd MMM yyyy)	UN AUG 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)	AUG 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) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	BILATERAL IMPAIRED VISION
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	ALCOHOL CONSUMPTION 1-2 TIMES PER WEEK
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Condition	OBESITY
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 (18)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:05
Height (xxx.x)	69.1 in
Weight (xxx.x)	353 lb
BMI (xxx.x)	52.08690 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:39:39

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 23:39:39

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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) 20 Feb 2021 23:39:39

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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) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 23:39:39

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What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 144912

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) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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)	25 AUG 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:05
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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)	25 AUG 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:38
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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) 20 Feb 2021 23:39:39

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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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 10:08

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) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

25 AUG 2020 09:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:43	25 AUG 2020 09:43
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:39

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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 13:37:16

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 10:44

PC Open Date & Time

25 AUG 2020 10:28

PC Close Date & Time

25 AUG 2020 12:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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 97.7 °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	25 AUG 2020 19:50
PC Open Date & Time	25 AUG 2020 13:53
PC Close Date & Time	26 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 15:17

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 21:18

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 06:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 04:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

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

96.5 °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

31 AUG 2020 06:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 10:45

PC Open Date & Time

25 AUG 2020 10:28

PC Close Date & Time

25 AUG 2020 12:58

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 19:51

PC Open Date & Time

25 AUG 2020 13:53

PC Close Date & Time

26 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 15:17

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 21:18

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 06:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 04:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 06:34

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 10:45
PC Open Date & Time	25 AUG 2020 10:28
PC Close Date & Time	25 AUG 2020 12:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 19:52
PC Open Date & Time	25 AUG 2020 13:53
PC Close Date & Time	26 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

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 ☒

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 15:18
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

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)

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 21:18
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

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 ☒

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 06:18
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 04:03
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

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 ☒

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 06:34
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:01
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3812257

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 22:00:10

Generated On: 12 Aug 2021 13:37:16

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)	23 SEP 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:47
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 22:00:10

Generated On: 12 Aug 2021 13:37:16

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	

US3812257

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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.

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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?

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?

US3812257

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

09:20 (24 HR)

Collection date and time (derived)

23 SEP 2020 09:20

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:25	23 SEP 2020 09:25
Nasopharyngeal Swab 2	No		

US3812257

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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

INADVERTENTLY NOT
COMPLETED PD WILL BE
NOTED

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 16:45
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)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812257

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

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.

US3812257

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

17:00 (24 HR)

Collection date and time (derived)

19 OCT 2020 17:00

US3812257

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:39

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 09:40:56

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

01 NOV 2020 05:48:56

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 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	12 NOV 2020 14:47:34
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 17:01:00

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 04:46:13
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

03 DEC 2020 10:19:41

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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	11 DEC 2020 14:22:24
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

17 DEC 2020 03:38:56

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	26 DEC 2020 09:10:04
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 10:58:54

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

10 JAN 2021 10:17:06

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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	15 JAN 2021 18:42:46
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

21 JAN 2021 09:52:02

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 12:57:06

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 14:49:01
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

14 FEB 2021 07:45:52

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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	21 FEB 2021 09:40:59
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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	28 FEB 2021 13:33:58
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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	04 MAR 2021 05:01:02
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 14:50:23

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

18 MAR 2021 19:58:40

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 09:42:04

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

01 APR 2021 17:52:01

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

10 APR 2021 19:56:43

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 06:09:03

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

22 APR 2021 12:02:24

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 04:47:39

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 264

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐ Yes ☐

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐ Yes ☐

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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13 JAN 2022 00:01

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17 JAN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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07 FEB 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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14 FEB 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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21 MAR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

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Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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 ☐ Yes ☐

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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15 AUG 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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22 AUG 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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05 SEP 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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08 SEP 2022 00:01

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12 SEP 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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15 SEP 2022 00:01

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19 SEP 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3812257

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:37:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 13:35:19

US3812257

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

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

Visit date (dd MMM yyyy)	08 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 00:49:19

Generated On: 12 Aug 2021 13:37:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 MAR 2021
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 15:16
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812257

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

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.

US3812257

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 MAR 2021

Collection time (00:00-23:59)

15:30 (24 HR)

Collection date and time (derived)

08 MAR 2021 15:30

US3812257

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Date of Contact	25 AUG 2020
Time of Contact	08:20
Date and Time of Contact (derived)	25 AUG 2020 08:20
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Date of Contact	30 DEC 2020
Time of Contact	16:45
Date and Time of Contact (derived)	30 DEC 2020 16:45
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>

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	23 DEC 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

300 of 2546

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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"/>

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	24 DEC 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 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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 30 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	25 DEC 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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Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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 30 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" 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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	26 DEC 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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Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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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Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" 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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	27 DEC 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 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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 30 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	28 DEC 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 30 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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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Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	29 DEC 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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Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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 30 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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 30 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 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"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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 30 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	01 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 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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EAB) (1725)

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	02 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.7 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 23:39:37

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	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 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 30 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	03 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 23:39:37

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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 30 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	04 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 23:39:37

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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 30 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	05 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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 30 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	06 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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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Form: Symptom Log (15)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

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Form: Symptom Log (16)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	07 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 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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US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	08 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

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 ☐

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input 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 checked="" 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"/>

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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	09 JAN 2021
------	-------------

Assessment Not Done	False
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O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 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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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

	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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EAB) (1725)

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 20 Feb 2021 23:39:37

Generated On: 12 Aug 2021 13:37:16

Date of Visit	30 DEC 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	30 DEC 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

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	01 JAN 2021
Day 5	Yes	03 JAN 2021
Day 7	Yes	05 JAN 2021
Day 9	Yes	07 JAN 2021
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3812257

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 DEC 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

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 DEC 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	30 DEC 2020 17:12
Height (xxx.x)	69.1 in
Weight (xxx.x)	360.6 lb
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812257

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3812257

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 DEC 2020

US3812257

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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

Visit date (dd MMM yyyy)	01 FEB 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3812257

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 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>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3812257

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Height	69.1 in
Weight	350.8 lb
BMI (xxx.x)	51.76228

US3812257

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Height	69.1 in
Weight	350.8 lb
BMI (xxx.x)	51.76228
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 FEB 2021
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 08:37
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3812257

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Height	69.1 in
Weight	350.8 lb
BMI (xxx.x)	51.76228
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)	01 FEB 2021
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 10:08
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812257

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

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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.

US3812257

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

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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 SUBJECT IS DELAYED CURRENTLY BEING TREATED FOR ACUTE EAR INFECTION. PER SUBJECT, STILL TAKING ANTIBIOTICS

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

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 01 FEB 2021 09:38

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

US3812257

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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

Collection date (dd MMM yyyy)	01 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	01 FEB 2021 09:05
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US3812257

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00 - 23:59)	09:10
Collection Date and Time (derived)	01 FEB 2021 09:10

US3812257

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

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:39:38

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

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

Visit date (dd MMM yyyy)	08 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 MAR 2021
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 15:16
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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	08 MAR 2021
Time of assessment (00:00-23:59)	16:11 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 16:11
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3812257

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

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.

US3812257

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

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) 08 MAR 2021

What was the treatment time? (00:00-23:59) 15:39 (24 HR)

Treatment Date and Time (derived) 08 MAR 2021 15:39

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

US3812257

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812257

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812257

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3812257

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3812257

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

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.

US3812257

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3812257

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 23:39:16

Generated On: 12 Aug 2021 13:37:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

AEID

Adverse event

BILATERAL OTITIS MEDIA

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)

30 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 JAN 2021

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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US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

AEID	
Adverse event	DIPLACUSIS
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)	30 DEC 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)	15 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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 (2)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

AEID	
Adverse event	COVID-19 INFECTION
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)	25 AUG 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)	11 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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 (3)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

AEID	
Adverse event	LACERATION RIGHT HAND
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)	21 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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 (4)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

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

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 23:39:17

Generated On: 12 Aug 2021 13:37:16

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

Yes ☒

No ☐

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

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT BILATERAL FEET AND KNEES

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN AUG 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 80

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) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2005	
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) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication POTASSIUM DEFICIENCY

Dose per administration 20

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

If dose unit is Other, specify MEQ

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) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication SEASONAL/ENVIRONMENTAL ALLERGIES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL OTITIS MEDIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL OTITIS MEDIA

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 (12)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 JAN 2021	
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 (13)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

Name of Medication KEFLEX

Prophylaxis Yes ☐
No ☒

Indication RIGHT HAND LACERATION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 15:16:46

Generated On: 12 Aug 2021 13:37:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 23:39:17

Generated On: 12 Aug 2021 13:37:16

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Mar 2021 20:22:23

Generated On: 12 Aug 2021 13:37:16

Date of dosing discontinuation (dd MMM yyyy) 23 SEP 2020

Primary reason for dosing discontinuation

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

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:37:16

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

US3812257 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812257

Form: Participant Creation

Generated On: 12 Aug 2021 13:37:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'US3812257'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	25 Aug 2020 14:14:58

US3812257

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	25 Aug 2020 15:32:08

US3812257

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:14:59

US3812257

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic (Clinic)'	Heather Cherniawski	25 Aug 2020 15:32:08

US3812257

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'SCRN'	System	25 Aug 2020 15:32:08

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:15:01

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '52'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'YEARS'	System	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '52'	System	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Male (M)'	Heather Cherniawski (b) (4)	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'I'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski (b) (4)	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski (b) (4)	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:37:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Heather Cherniawski	25 Aug 2020 15:35:35

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	Heather Cherniawski	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2020'	System	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2020'	System	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Amendment 2 (2)'	Heather Cherniawski	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Heather Cherniawski	25 Aug 2020 15:32:24

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:14:59

US3812257

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:37:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'I'	System	25 Aug 2020 15:32:33

US3812257

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	25 Aug 2020 15:32:33

US3812257

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:37:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:18:41

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:21:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:21:53
Data point term sent to Coder	System	03 Sep 2020 20:20:43
User entered 'myocardial infarction'	(b) (4), (b) (6)	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Aug 2012'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Aug 2012'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2012'	System	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2012'	System	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2012'	System	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2012'	System	03 Sep 2020 20:19:47

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 07:14:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 07:14:30
Data point term sent to Coder	System	03 Sep 2020 20:21:45
User entered 'left carpal tunnel repair'	(b) (4), (b) (6)	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Mar 2020'	System	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2020'	System	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Mar 2020'	System	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2020'	System	03 Sep 2020 20:20:55

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Contrast media allergy, LLT: Contrast media allergy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:56:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:56:46
Data point term sent to Coder	System	03 Sep 2020 20:23:50
User entered 'lipid microsphere allergy'	(b) (4), (b) (6)	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Aug 2012'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2012'	System	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2012'	System	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:23:40

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:25:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:25:45
Data point term sent to Coder	System	03 Sep 2020 20:24:51
User entered 'coconut allergy'	(b) (4), (b) (6)	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 1977'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 1977'	System	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '1977'	System	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:24:07

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 07:14:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 07:14:30
Data point term sent to Coder	System	03 Sep 2020 20:25:52
User entered 'left carpel tunnel'	(b) (4), (b) (6)	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Mar 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 2010'	System	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2010'	System	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Mar 2020'	System	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2020'	System	03 Sep 2020 20:25:41

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 07:53:16
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Anya Penly Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	29 Oct 2020 14:01:23
' answered with 'Please not subject is on 80 mg of furosemide which is a dosage commonly used for CHF however subject reported conmed taken for HTN and site has yet to receive medical records to support the use of furosemide for the subject's medical condition of CHF' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	28 Sep 2020 09:14:28
' (Site from DM).		
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:28:43
Data point term sent to Coder	System	03 Sep 2020 20:27:55
User entered 'congestive heart failure'	(b) (4), (b) (6)	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Aug 2012'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2012'	System	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2012'	System	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:27:17

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:28:43
Data point term sent to Coder	System	03 Sep 2020 20:27:58
User entered 'gastric bypass'	(b) (4), (b) (6)	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Dec 2018'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Dec 2018'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Dec 2018'	System	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2018'	System	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Dec 2018'	System	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2018'	System	03 Sep 2020 20:27:55

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:29:44
Data point term sent to Coder	System	03 Sep 2020 20:28:59
User entered 'hypertension'	(b) (4), (b) (6)	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Jun 2005'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jun 2005'	System	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2005'	System	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:28:15

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:30:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:30:45
Data point term sent to Coder	System	03 Sep 2020 20:30:02
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un Aug 2012'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2012'	System	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2012'	System	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:29:23

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 12:22:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 03:51:30
Data point term sent to Coder	System	29 Oct 2020 14:08:25
Query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated with location' (Site from DM).	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:08:13
Coding entries removed.	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:08:06
User entered 'GOUT bilateral feet and knees' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:08:06
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 09:14:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:31:47

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EAB) (1725)

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Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	03 Sep 2020 20:31:06
User entered 'gout'	(b) (4), (b) (6)	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 2005'	System	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2005'	System	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:30:44

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Potassium deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:31:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:31:49
Data point term sent to Coder	System	03 Sep 2020 20:31:08
User entered 'potassium deficiency'	(b) (4), (b) (6)	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'UN Aug 2012' reason for change:	(b) (4)	
Data Entry Error	Anya Penly (b) (4)	30 Oct 2020 22:38:44
User entered 'un Aug 2017'	(b) (4), (b) (6)	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Aug 2012'	System	30 Oct 2020 22:38:44
User entered 'Aug 2017'	System	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2012'	System	30 Oct 2020 22:38:44
User entered '2017'	System	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:31:06

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH# 12 SEASONAL ALLERGIES with start date of UN UNK 1977. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 12:22:54
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH# 12 SEASONAL ALLERGIES with start date of UN UNK 1977. If yes, please ensure only one entry is recorded. ' answered with 'inactivated duplicate line 12' (Site from DM).	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:09:13
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH# 12 SEASONAL ALLERGIES with start date of UN UNK 1977. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:21:21
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:33:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:33:42
Data point term sent to Coder	System	03 Sep 2020 20:32:12
User entered 'environmental allergies'	(b) (4), (b) (6)	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 1977'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 1977'	System	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '1977'	System	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:32:08

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:33:44
Data point term sent to Coder	System	03 Sep 2020 20:33:13
User entered 'sleep apnea'	(b) (4), (b) (6)	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 2005'	System	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2005'	System	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:32:22

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 22:18:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 22:18:47
Data point term sent to Coder	System	03 Sep 2020 20:46:22
User entered 'bilateral impaired vision'	(b) (4), (b) (6)	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 1972'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 1972'	System	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '1972'	System	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:45:23

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Social circumstances, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 20:50:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 20:50:49
Data point term sent to Coder	System	03 Sep 2020 20:46:23
User entered 'alcohol consumption 1-2 times per week'	(b) (4), (b) (6)	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 1988'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 1988'	System	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '1988'	System	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:45:59

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:47:44
Data point term sent to Coder	System	03 Sep 2020 20:47:26
User entered 'obesity'	(b) (4), (b) (6)	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 2010'	System	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2010'	System	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (17)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:46:26

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Per MM, please include the underlying condition that led to the procedure.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 12:23:19
Query 'Per MM, please include the underlying condition that led to the procedure.' answered with 'subject has MH of sleep apnea' (Site from DM).	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:09:55
User opened query 'Per MM, please include the underlying condition that led to the procedure.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:50:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Respiratory tract therapeutic procedures NEC, PT: Continuous positive airway pressure, LLT: CPAP - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:51:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:51:34
Data point term sent to Coder	System	03 Sep 2020 20:48:29
User entered 'CPAP usage'	(b) (4), (b) (6)	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'Jan 2005'	System	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '2005'	System	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Medical History (18)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered empty.	System	03 Sep 2020 20:47:31

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:05'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '25 Aug 2020 09:05'	System	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '69.1' in	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00
DataPoint set to visible.	System	25 Aug 2020 15:32:33

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '353' lb	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00
DataPoint set to visible.	System	25 Aug 2020 15:32:33

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered '52.08690'	System	03 Sep 2020 20:49:00
DataPoint set to visible.	System	25 Aug 2020 15:32:33

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'kg/m2'	System	03 Sep 2020 20:49:00
DataPoint set to visible.	System	25 Aug 2020 15:32:33

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'bpm'	System	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'breaths/min'	System	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'mmHg'	System	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User entered 'mmHg'	System	03 Sep 2020 20:49:00

US3812257

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13

US3812257

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:49:18

US3812257

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:49:18

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:50:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:50:32
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:50:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:37:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:00:13
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:50:13

US3812257

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	25 Aug 2020 15:32:46

US3812257

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	Heather Cherniawski	25 Aug 2020 15:32:46

US3812257

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[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 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic (Clinic)'	Heather Cherniawski	25 Aug 2020 15:32:46

US3812257

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'VISIT1'	System	25 Aug 2020 15:32:46

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:39:26

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '144912'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:39:26

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:39:26

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

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 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4)	11 Sep 2020 18:51:53
Query 'PER CDM: Please complete this section of the form.' answered with 'completed per query' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 20:52:04
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:51:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:51:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:51:31
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 20:51:14
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:51:14
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:16:54

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

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 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:51:14

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:51:14

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:51:31
User entered 'No (N)' reason for change: Data Entry Error	System	03 Sep 2020 20:51:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 20:51:14
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:51:14

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 20:51:31
User entered 'No (N)' reason for change: Data Entry Error	System	03 Sep 2020 20:51:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 20:51:14
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:51:14

US3812257

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:37:16

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Breanna Galibert (b) (4)	21 Sep 2020 18:54:48
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:49:38

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:05'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered '25 Aug 2020 09:05'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97.7' F	(b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '80'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'bpm'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '14'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'breaths/min'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '136'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'mmHg'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '86'	(b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'mmHg'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '10:38'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered '25 Aug 2020 10:38'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97.2' F	(b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	03 Sep 2020 20:55:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	03 Sep 2020 20:55:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 20:55:10
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 20:54:56
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '73'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'bpm'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'breaths/min'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '134'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'mmHg'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '78'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'mmHg'	System	03 Sep 2020 20:54:56

US3812257

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:55:41

US3812257

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:55:41

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

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 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski (b) (4)	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	Heather Cherniawski	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '10:08'	Heather Cherniawski	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered '25 Aug 2020 10:08'	System	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Right Arm (RIGHT ARM)'	Heather Cherniawski	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'ONCE'	System	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 15:33:49

US3812257

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:56:46

US3812257

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:56:46

US3812257

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:40'	(b) (4), (b) (6)	03 Sep 2020 20:56:46

US3812257

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered '25 Aug 2020 09:40'	System	03 Sep 2020 20:56:46

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:37:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:43'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered '25 Aug 2020 09:43'	System	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered empty.	System	03 Sep 2020 20:57:11

US3812257

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:14:48

US3812257

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'I'	System	03 Sep 2020 20:14:48

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:44:16', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1541aa7c-0f8c-4e6d-9a86-b2baaa8ca1b2'	System	25 Aug 2020 15:47:50
User entered 'Yes (Y)'	System	25 Aug 2020 15:47:50

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:44:21', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1541aa7c-0f8c-4e6d-9a86-b2baaa8ca1b2'	System	25 Aug 2020 15:47:50
User entered '97.2'	System	25 Aug 2020 15:47:50

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:44:27', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1541aa7c-0f8c-4e6d-9a86-b2baaa8ca1b2'	System	25 Aug 2020 15:47:50
User entered 'No (N)'	System	25 Aug 2020 15:47:50

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:44:43', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1541aa7c-0f8c-4e6d-9a86-b2baaa8ca1b2'	System	25 Aug 2020 15:47:50
User entered '25 Aug 2020 10:44'	System	25 Aug 2020 15:47:50

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 10:28'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 12:58'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:50:28', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e9ea1919-dc2d-46c5-ba21-bddf372da1ac'	System	26 Aug 2020 00:53:52
User entered 'Yes (Y)'	System	26 Aug 2020 00:53:52

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:50:36', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e9ea1919-dc2d-46c5-ba21-bddf372da1ac'	System	26 Aug 2020 00:53:52
User entered '97.7'	System	26 Aug 2020 00:53:52

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:50:40', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e9ea1919-dc2d-46c5-ba21-bddf372da1ac'	System	26 Aug 2020 00:53:52
User entered 'No (N)'	System	26 Aug 2020 00:53:52

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:50:45', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e9ea1919-dc2d-46c5-ba21-bddf372da1ac'	System	26 Aug 2020 00:53:52
User entered '25 Aug 2020 19:50'	System	26 Aug 2020 00:53:52

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 13:53'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 2'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:16:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'b7e0e786-5aa3-46df-b647-f744e62d5c68'	System	26 Aug 2020 20:20:10
User entered 'Yes (Y)'	System	26 Aug 2020 20:20:10

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:16:58', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'b7e0e786-5aa3-46df-b647-f744e62d5c68'	System	26 Aug 2020 20:20:10
User entered '98.4'	System	26 Aug 2020 20:20:10

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:01', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'b7e0e786-5aa3-46df-b647-f744e62d5c68'	System	26 Aug 2020 20:20:10
User entered 'No (N)'	System	26 Aug 2020 20:20:10

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:04', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'b7e0e786-5aa3-46df-b647-f744e62d5c68'	System	26 Aug 2020 20:20:10
User entered '26 Aug 2020 15:17'	System	26 Aug 2020 20:20:10

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 3'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:17:48', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1462d335-ad48-4208-b38f-03a14250f6a0'	System	28 Aug 2020 02:21:13
User entered 'Yes (Y)'	System	28 Aug 2020 02:21:13

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:17:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1462d335-ad48-4208-b38f-03a14250f6a0'	System	28 Aug 2020 02:21:13
User entered '97.9'	System	28 Aug 2020 02:21:13

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:02', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1462d335-ad48-4208-b38f-03a14250f6a0'	System	28 Aug 2020 02:21:13
User entered 'No (N)'	System	28 Aug 2020 02:21:13

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:04', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1462d335-ad48-4208-b38f-03a14250f6a0'	System	28 Aug 2020 02:21:13
User entered '27 Aug 2020 21:18'	System	28 Aug 2020 02:21:13

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 4'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:18', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '85bf0bc7-8c1e-47b4-9f11-92d040101fd4'	System	29 Aug 2020 11:20:41
User entered 'Yes (Y)'	System	29 Aug 2020 11:20:41

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:26', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '85bf0bc7-8c1e-47b4-9f11-92d040101fd4'	System	29 Aug 2020 11:20:41
User entered '97.9'	System	29 Aug 2020 11:20:41

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:29', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '85bf0bc7-8c1e-47b4-9f11-92d040101fd4'	System	29 Aug 2020 11:20:41
User entered 'No (N)'	System	29 Aug 2020 11:20:41

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:32', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '85bf0bc7-8c1e-47b4-9f11-92d040101fd4'	System	29 Aug 2020 11:20:41
User entered '29 Aug 2020 06:17'	System	29 Aug 2020 11:20:41

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 5'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:02:47', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4485ed62-87ee-4bd0-89e7-bcc94c45a24f'	System	30 Aug 2020 09:06:08
User entered 'Yes (Y)'	System	30 Aug 2020 09:06:08

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:02:52', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4485ed62-87ee-4bd0-89e7-bcc94c45a24f'	System	30 Aug 2020 09:06:08
User entered '98.2'	System	30 Aug 2020 09:06:08

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:02:55', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4485ed62-87ee-4bd0-89e7-bcc94c45a24f'	System	30 Aug 2020 09:06:08
User entered 'No (N)'	System	30 Aug 2020 09:06:08

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:02:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4485ed62-87ee-4bd0-89e7-bcc94c45a24f'	System	30 Aug 2020 09:06:08
User entered '30 Aug 2020 04:02'	System	30 Aug 2020 09:06:08

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 6'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:33:46', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1f55e534-5cc6-419b-b0f2-52c7304982a3'	System	31 Aug 2020 11:37:05
User entered 'Yes (Y)'	System	31 Aug 2020 11:37:05

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:33:50', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1f55e534-5cc6-419b-b0f2-52c7304982a3'	System	31 Aug 2020 11:37:05
User entered '96.5'	System	31 Aug 2020 11:37:05

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:33:54', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1f55e534-5cc6-419b-b0f2-52c7304982a3'	System	31 Aug 2020 11:37:05
User entered 'No (N)'	System	31 Aug 2020 11:37:05

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:33:56', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1f55e534-5cc6-419b-b0f2-52c7304982a3'	System	31 Aug 2020 11:37:05
User entered '31 Aug 2020 06:33'	System	31 Aug 2020 11:37:05

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 7'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:00:58', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '977d6b2c-5ae7-4b10-b619-ef793e0e1820'	System	31 Aug 2020 17:15:40
User entered 'Yes (Y)'	System	31 Aug 2020 17:15:40

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:02', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '977d6b2c-5ae7-4b10-b619-ef793e0e1820' User entered '98.1'	System	31 Aug 2020 17:15:40
	System	31 Aug 2020 17:15:40

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:05', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '977d6b2c-5ae7-4b10-b619-ef793e0e1820'	System	31 Aug 2020 17:15:40
User entered 'No (N)'	System	31 Aug 2020 17:15:40

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:09', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '977d6b2c-5ae7-4b10-b619-ef793e0e1820'	System	31 Aug 2020 17:15:40
User entered '31 Aug 2020 12:01'	System	31 Aug 2020 17:15:40

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:44:57', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfe770aa-11ac-474f-96a9-eb248ec524a0'	System	25 Aug 2020 15:48:20
User entered 'None (1)'	System	25 Aug 2020 15:48:20

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:01', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfe770aa-11ac-474f-96a9-eb248ee524a0'	System	25 Aug 2020 15:48:20
User entered 'No (N)'	System	25 Aug 2020 15:48:20

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:04', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfe770aa-11ac-474f-96a9-eb248ee524a0'	System	25 Aug 2020 15:48:20
User entered 'No (N)'	System	25 Aug 2020 15:48:20

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:10', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfe770aa-11ac-474f-96a9-eb248ec524a0'	System	25 Aug 2020 15:48:20
User entered 'None (1)'	System	25 Aug 2020 15:48:20

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:15', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfe770aa-11ac-474f-96a9-eb248ee524a0'	System	25 Aug 2020 15:48:20
User entered '25 Aug 2020 10:45'	System	25 Aug 2020 15:48:20

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 10:28'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 12:58'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:50:53', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f5da19ed-8996-4783-98df-134c83f88d6b'	System	26 Aug 2020 00:54:34
User entered 'None (1)'	System	26 Aug 2020 00:54:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:09', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f5da19ed-8996-4783-98df-134c83f88d6b'	System	26 Aug 2020 00:54:34
User entered 'No (N)'	System	26 Aug 2020 00:54:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:12', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f5da19ed-8996-4783-98df-134c83f88d6b'	System	26 Aug 2020 00:54:34
User entered 'No (N)'	System	26 Aug 2020 00:54:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:20', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f5da19ed-8996-4783-98df-134c83f88d6b'	System	26 Aug 2020 00:54:34
User entered 'None (1)'	System	26 Aug 2020 00:54:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:26', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f5da19ed-8996-4783-98df-134c83f88d6b'	System	26 Aug 2020 00:54:34
User entered '25 Aug 2020 19:51'	System	26 Aug 2020 00:54:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 13:53'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 2'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:08', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c717ae3a-7f72-4ea7-8f56-cc06383844c8'	System	26 Aug 2020 20:20:27
User entered 'None (1)'	System	26 Aug 2020 20:20:27

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:10', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c717ae3a-7f72-4ea7-8f56-cc06383844c8'	System	26 Aug 2020 20:20:27
User entered 'No (N)'	System	26 Aug 2020 20:20:27

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:13', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c717ae3a-7f72-4ea7-8f56-cc06383844c8'	System	26 Aug 2020 20:20:27
User entered 'No (N)'	System	26 Aug 2020 20:20:27

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:18', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c717ae3a-7f72-4ea7-8f56-cc06383844c8'	System	26 Aug 2020 20:20:27
User entered 'None (1)'	System	26 Aug 2020 20:20:27

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:21', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c717ae3a-7f72-4ea7-8f56-cc06383844c8'	System	26 Aug 2020 20:20:27
User entered '26 Aug 2020 15:17'	System	26 Aug 2020 20:20:27

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 3'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:09', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '022af08b-5eaf-4e20-8cf1-6224e7e6f2e5'	System	28 Aug 2020 02:21:40
User entered 'None (1)'	System	28 Aug 2020 02:21:40

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:11', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '022af08b-5eaf-4e20-8cf1-6224e7e6f2e5'	System	28 Aug 2020 02:21:40
User entered 'No (N)'	System	28 Aug 2020 02:21:40

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:14', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '022af08b-5eaf-4e20-8cf1-6224e7e6f2e5'	System	28 Aug 2020 02:21:40
User entered 'No (N)'	System	28 Aug 2020 02:21:40

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:29', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '022af08b-5eaf-4e20-8cf1-6224e7e6f2e5'	System	28 Aug 2020 02:21:40
User entered 'None (1)'	System	28 Aug 2020 02:21:40

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:32', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '022af08b-5eaf-4e20-8cf1-6224e7e6f2e5'	System	28 Aug 2020 02:21:40
User entered '27 Aug 2020 21:18'	System	28 Aug 2020 02:21:40

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 4'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:37', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8c3f1164-6ce8-4f96-88b2-3d0ea5e8f09c'	System	29 Aug 2020 11:20:59
User entered 'None (1)'	System	29 Aug 2020 11:20:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:40', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8c3f1164-6ce8-4f96-88b2-3d0ea5e8f09c'	System	29 Aug 2020 11:20:59
User entered 'No (N)'	System	29 Aug 2020 11:20:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:43', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8c3f1164-6ce8-4f96-88b2-3d0ea5e8f09c'	System	29 Aug 2020 11:20:59
User entered 'No (N)'	System	29 Aug 2020 11:20:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:46', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8c3f1164-6ce8-4f96-88b2-3d0ea5e8f09c'	System	29 Aug 2020 11:20:59
User entered 'None (1)'	System	29 Aug 2020 11:20:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:49', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8c3f1164-6ce8-4f96-88b2-3d0ea5e8f09c'	System	29 Aug 2020 11:20:59
User entered '29 Aug 2020 06:17'	System	29 Aug 2020 11:20:59

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 5'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:04', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a2348f6c-76c1-454d-876f-5baba2335807'	System	30 Aug 2020 09:06:23
User entered 'None (1)'	System	30 Aug 2020 09:06:23

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:06', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a2348f6c-76c1-454d-876f-5baba2335807'	System	30 Aug 2020 09:06:23
User entered 'No (N)'	System	30 Aug 2020 09:06:23

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:09', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a2348f6c-76c1-454d-876f-5baba2335807'	System	30 Aug 2020 09:06:23
User entered 'No (N)'	System	30 Aug 2020 09:06:23

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:11', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a2348f6c-76c1-454d-876f-5baba2335807'	System	30 Aug 2020 09:06:23
User entered 'None (1)'	System	30 Aug 2020 09:06:23

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:14', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a2348f6c-76c1-454d-876f-5baba2335807'	System	30 Aug 2020 09:06:23
User entered '30 Aug 2020 04:03'	System	30 Aug 2020 09:06:23

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 6'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:03', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '7bc04467-c838-42f0-a42d-deca133473e8'	System	31 Aug 2020 11:37:34
User entered 'None (1)'	System	31 Aug 2020 11:37:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:06', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '7bc04467-c838-42f0-a42d-deca133473e8'	System	31 Aug 2020 11:37:34
User entered 'No (N)'	System	31 Aug 2020 11:37:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:08', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '7bc04467-c838-42f0-a42d-deca133473e8'	System	31 Aug 2020 11:37:34
User entered 'No (N)'	System	31 Aug 2020 11:37:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:20', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '7bc04467-c838-42f0-a42d-deca133473e8'	System	31 Aug 2020 11:37:34
User entered 'None (1)'	System	31 Aug 2020 11:37:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:23', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '7bc04467-c838-42f0-a42d-deca133473e8'	System	31 Aug 2020 11:37:34
User entered '31 Aug 2020 06:34'	System	31 Aug 2020 11:37:34

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 7'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:12', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'feb6c5e7-8deb-4e30-b3e7-1da2b0b6d645'	System	31 Aug 2020 17:15:47
User entered 'None (1)'	System	31 Aug 2020 17:15:47

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:15', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'feb6c5e7-8deb-4e30-b3e7-1da2b0b6d645'	System	31 Aug 2020 17:15:47
User entered 'No (N)'	System	31 Aug 2020 17:15:47

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:17', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'feb6c5e7-8deb-4e30-b3e7-1da2b0b6d645'	System	31 Aug 2020 17:15:47
User entered 'No (N)'	System	31 Aug 2020 17:15:47

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:19', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'feb6c5e7-8deb-4e30-b3e7-1da2b0b6d645'	System	31 Aug 2020 17:15:47
User entered 'None (1)'	System	31 Aug 2020 17:15:47

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:22', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'feb6c5e7-8deb-4e30-b3e7-1da2b0b6d645'	System	31 Aug 2020 17:15:47
User entered '31 Aug 2020 12:01'	System	31 Aug 2020 17:15:47

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:28', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'None (0)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:31', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'None (0)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:36', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'None (0)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:41', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'None (0)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:43', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'None (0)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:46', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'None (0)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:52', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered 'No (N)'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T10:45:57', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '0e4a1d9b-9491-4b97-af47-2614f0dde5ed'	System	25 Aug 2020 15:49:03
User entered '25 Aug 2020 10:45'	System	25 Aug 2020 15:49:03

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 10:28'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 12:58'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:40', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'None (0)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:43', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'None (0)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:46', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'None (0)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:49', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'None (0)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'None (0)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:53', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'None (0)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:51:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered 'No (N)'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-25T19:52:02', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'dfdd973d-27ee-4fa4-8620-e16832a7842d'	System	26 Aug 2020 00:55:09
User entered '25 Aug 2020 19:52'	System	26 Aug 2020 00:55:09

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '25 Aug 2020 13:53'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 2'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:42', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'No interference with activity (1)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:48', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'No interference with activity (1)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'None (0)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:54', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'None (0)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:57', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'None (0)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:17:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'None (0)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:18:12', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered 'No (N)'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-26T15:18:19', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4aaf66a1-2630-4dda-90e6-2604ee99fc9a'	System	26 Aug 2020 20:21:29
User entered '26 Aug 2020 15:18'	System	26 Aug 2020 20:21:29

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 3'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:37', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'None (0)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:43', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'None (0)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:46', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'None (0)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:49', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'None (0)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'None (0)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:53', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'None (0)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:57', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered 'No (N)'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-27T21:18:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '049d15da-b4e1-43c4-8ec1-7798bda3ba3c'	System	28 Aug 2020 02:22:08
User entered '27 Aug 2020 21:18'	System	28 Aug 2020 02:22:08

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 4'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:17:56', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'None (0)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:05', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'No interference with activity (1)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:07', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'None (0)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:09', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'None (0)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:13', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'None (0)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:15', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'None (0)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:18', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered 'No (N)'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-29T06:18:22', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '01e4bb6b-4056-4b8c-9e20-354a7deaf1d9'	System	29 Aug 2020 11:21:31
User entered '29 Aug 2020 06:18'	System	29 Aug 2020 11:21:31

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 5'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:25', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'None (0)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:27', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'None (0)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:29', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'None (0)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:31', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'None (0)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:33', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'None (0)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:34', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'None (0)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:38', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered 'No (N)'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-30T04:03:41', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd06ffb8f-73ef-4a5e-9a9c-ab65123ba9e4'	System	30 Aug 2020 09:06:50
User entered '30 Aug 2020 04:03'	System	30 Aug 2020 09:06:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 6'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:32', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'None (0)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:35', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'None (0)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:37', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'None (0)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:40', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'None (0)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:42', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'None (0)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:44', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'None (0)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:47', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered 'No (N)'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T06:34:49', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f3abe46f-a1fe-45b2-a907-ea84a3b059a4'	System	31 Aug 2020 11:37:58
User entered '31 Aug 2020 06:34'	System	31 Aug 2020 11:37:58

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 7'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:25', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'None (0)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:27', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'None (0)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:28', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'None (0)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:30', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'None (0)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:33', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'None (0)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:35', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'None (0)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:39', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered 'No (N)'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-08-31T12:01:42', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '957d9830-25ef-4086-9598-2894456c5f39'	System	31 Aug 2020 17:15:50
User entered '31 Aug 2020 12:01'	System	31 Aug 2020 17:15:50

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:33:49

US3812257

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:37:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:15:02

US3812257

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '03 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	10 Nov 2020 23:20:44
User entered '3 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:15:02

US3812257

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:15:02

US3812257

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:15:02

US3812257

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:01:20

US3812257

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'I'	System	08 Sep 2020 21:01:20

US3812257

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:01:33

US3812257

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '08 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	10 Nov 2020 23:20:53
User entered '8 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	08 Sep 2020 21:01:33

US3812257

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:01:33

US3812257

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:01:33

US3812257

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Sep 2020 12:21:25

US3812257

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:58
User entered 'I'	System	13 Sep 2020 12:21:25

US3812257

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Sep 2020 16:58:17

US3812257

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '15 Sep 2020'	Karen Knapp (b) (4)	15 Sep 2020 16:58:17

US3812257

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	15 Sep 2020 16:58:17

US3812257

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	15 Sep 2020 16:58:17

US3812257

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Sep 2020 16:58:21

US3812257

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:04:34
User entered 'I'	System	15 Sep 2020 16:58:21

US3812257

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:10:40

US3812257

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:10:40

US3812257

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[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 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:10:40

US3812257

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'VISIT2'	System	28 Sep 2020 15:10:40

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '08:47'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered '23 Sep 2020 08:47'	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '80'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'bpm'	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'breaths/min'	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '152'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'mmHg'	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '96'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'mmHg'	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User closed query 'Please confirm if Post dose vitals were performed. Thank you' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 15:38:18
Query 'Please confirm if Post dose vitals were performed. Thank you' answered with 'no post dose vitals to obtain as subject was covid + at baseline and did not get second vaccine.' (Site from CRA).	Angie Kean (b) (4)	23 Feb 2021 00:40:36
User opened query 'Please confirm if Post dose vitals were performed. Thank you' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 15:40:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User closed query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:07:15
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	27 Oct 2020 00:45:41
Query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	27 Oct 2020 00:44:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	27 Oct 2020 00:40:52
User opened query 'Per CDM: As per Section 8.2.5 of Protocol, on Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection. Please confirm if the Post-dose VS assessments were performed. Else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:22:13
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
	System	27 Oct 2020 00:45:41
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	27 Oct 2020 00:45:41
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Oct 2020 00:44:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Oct 2020 00:44:29
User entered '19 Oct 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	27 Oct 2020 00:44:29
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Oct 2020 00:40:52
User entered '14 Sep 2020' reason for change: Data Entry Error	Angie Kean (b) (4)	27 Oct 2020 00:40:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
	(b) (4)	
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	27 Oct 2020 00:44:29
User entered '16:45' reason for change: Data Entry Error	Angie Kean (b) (4)	27 Oct 2020 00:44:29
	(b) (4)	
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	27 Oct 2020 00:40:52
User entered '09:48' reason for change: Data Entry Error	Angie Kean (b) (4)	27 Oct 2020 00:40:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	27 Oct 2020 00:45:41
User entered '19 Oct 2020 16:45'	System	27 Oct 2020 00:44:29
User entered '14 Sep 2020 09:48'	System	27 Oct 2020 00:40:52
User entered empty.	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:44:29
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:40:52
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
	(b) (4)	
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	27 Oct 2020 00:44:29
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	27 Oct 2020 00:40:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	Angie Kean (b) (4)	27 Oct 2020 00:40:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:44:29
User entered '61' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:40:52
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
User entered '88' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:44:29
User entered '61' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:40:52
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	27 Oct 2020 00:45:41
User entered 'bpm'	System	27 Oct 2020 00:40:52
User entered empty.	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
User entered '17' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:44:29
User entered '12' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:40:52
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	27 Oct 2020 00:45:41
User entered 'breaths/min'	System	27 Oct 2020 00:40:52
User entered empty.	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
User entered '134' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:44:29
User entered '119' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:40:52
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	27 Oct 2020 00:45:41
User entered 'mmHg'	System	27 Oct 2020 00:40:52
User entered empty.	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty; reason for change Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:45:41
User entered '80' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:44:29
User entered '88' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	27 Oct 2020 00:40:52
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	27 Oct 2020 00:45:41
User entered 'mmHg'	System	27 Oct 2020 00:40:52
User entered empty.	System	28 Sep 2020 15:12:50

US3812257

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:13:24

US3812257

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:13:24

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

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 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	28 Sep 2020 15:14:18

US3812257

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:52

US3812257

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:14:52

US3812257

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:20'	(b) (4), (b) (6)	28 Sep 2020 15:14:52

US3812257

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered '23 Sep 2020 09:20'	System	28 Sep 2020 15:14:52

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:37:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:25'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered '23 Sep 2020 09:25'	System	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered empty.	System	28 Sep 2020 15:15:22

US3812257

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Any Penly (b) (4)	07 Oct 2020 18:03:21

US3812257

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'I'	System	07 Oct 2020 18:03:21

US3812257

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Oct 2020 18:08:07

US3812257

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '7 Oct 2020'	Breanna Galibert (b) (4)	07 Oct 2020 18:08:07

US3812257

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	07 Oct 2020 18:08:07

US3812257

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	07 Oct 2020 18:08:07

US3812257

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	14 Oct 2020 14:27:10

US3812257

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'I'	System	14 Oct 2020 14:27:10

US3812257

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	14 Oct 2020 14:27:19

US3812257

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '14 Oct 2020'	Karen Knapp (b) (4)	14 Oct 2020 14:27:19

US3812257

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	14 Oct 2020 14:27:19

US3812257

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	14 Oct 2020 14:27:19

US3812257

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	14 Oct 2020 14:27:24

US3812257

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'I'	System	14 Oct 2020 14:27:24

US3812257

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Angie Kean (b) (4)	12 Dec 2020 00:15:23

US3812257

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Angie Kean (b) (4)	12 Dec 2020 00:15:23

US3812257

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Angie Kean (b) (4)	12 Dec 2020 00:15:23

US3812257

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Inadvertently not completed PD will be noted'	Angie Kean (b) (4)	12 Dec 2020 00:15:23

US3812257

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 14:47:31

US3812257

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'I'	System	23 Oct 2020 14:47:31

US3812257

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 14:47:42

US3812257

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	23 Oct 2020 14:47:42

US3812257

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[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 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	23 Oct 2020 14:47:42

US3812257

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'VISIT3'	System	23 Oct 2020 14:47:42

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '16:45'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered '19 Oct 2020 16:45'	System	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.0' F	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '88'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'bpm'	System	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '17'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'breaths/min'	System	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '134'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'mmHg'	System	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '80'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'mmHg'	System	23 Oct 2020 14:48:10

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34

US3812257

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34

US3812257

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:17

US3812257

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	23 Oct 2020 14:48:17

US3812257

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:29

US3812257

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:29

US3812257

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '17:00'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:29

US3812257

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered '19 Oct 2020 17:00'	System	23 Oct 2020 14:48:29

US3812257

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Oct 2020 14:48:33

US3812257

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'I'	System	23 Oct 2020 14:48:33

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 64'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-10-29T09:40:41', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd7c93cab-10b2-457e-ad1a-61afb87a3af2'	System	29 Oct 2020 14:44:23
User entered 'No (N)'	System	29 Oct 2020 14:44:23

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-10-29T09:40:50', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd7c93cab-10b2-457e-ad1a-61afb87a3af2'	System	29 Oct 2020 14:44:23
User entered 'No (N)'	System	29 Oct 2020 14:44:23

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-10-29T09:40:56', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd7c93cab-10b2-457e-ad1a-61afb87a3af2'	System	29 Oct 2020 14:44:23
User entered '29 Oct 2020 09:40:56'	System	29 Oct 2020 14:44:23

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 71'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-11-01T05:48:45', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'eb7245c1-5449-4f34-b964-2b036354530c'	System	01 Nov 2020 11:52:22
User entered 'No (N)'	System	01 Nov 2020 11:52:22

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-11-01T05:48:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'eb7245c1-5449-4f34-b964-2b036354530c'	System	01 Nov 2020 11:52:22
User entered 'No (N)'	System	01 Nov 2020 11:52:22

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3b2fbd3aa9872b67)', Time: '2020-11-01T05:48:56', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'eb7245c1-5449-4f34-b964-2b036354530c' User entered '01 Nov 2020 05:48:56'	System	01 Nov 2020 11:52:22
	System	01 Nov 2020 11:52:22

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered 'Day 78'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-11-12T14:47:25', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4f461458-899a-46b7-a18a-541a42c8862f'	System	12 Nov 2020 20:47:37
User entered 'No (N)'	System	12 Nov 2020 20:47:37

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-11-12T14:47:28', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4f461458-899a-46b7-a18a-541a42c8862f'	System	12 Nov 2020 20:47:37
User entered 'No (N)'	System	12 Nov 2020 20:47:37

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-11-12T14:47:34', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4f461458-899a-46b7-a18a-541a42c8862f'	System	12 Nov 2020 20:47:37
User entered '12 Nov 2020 14:47:34'	System	12 Nov 2020 20:47:37

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 15:33:49

US3812257

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:54:53
Data entry locked.	System	25 Aug 2020 15:33:49
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 15:33:49

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-11-22T17:00:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '92fb1d5b-ffc5-4d37-9f48-f675066dac58'	System	22 Nov 2020 23:01:08
User entered 'No (N)'	System	22 Nov 2020 23:01:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2020-11-22T17:00:56', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '92fb1d5b-ffc5-4d37-9f48-f675066dac58'	System	22 Nov 2020 23:01:08
User entered 'No (N)'	System	22 Nov 2020 23:01:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-11-22T17:01:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '92fb1d5b-ffc5-4d37-9f48-f675066dac58'	System	22 Nov 2020 23:01:08
User entered '22 Nov 2020 17:01:00'	System	22 Nov 2020 23:01:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-11-26T04:46:03', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ddaa8855-4eea-40dd-b1ad-026b935aea3d'	System	26 Nov 2020 10:46:16
User entered 'No (N)'	System	26 Nov 2020 10:46:16

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2020-11-26T04:46:09', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ddaa8855-4eea-40dd-b1ad-026b935aea3d'	System	26 Nov 2020 10:46:16
User entered 'No (N)'	System	26 Nov 2020 10:46:16

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-11-26T04:46:13', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ddaa8855-4eea-40dd-b1ad-026b935aea3d'	System	26 Nov 2020 10:46:16
User entered '26 Nov 2020 04:46:13'	System	26 Nov 2020 10:46:16

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-12-03T10:19:33', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'af211713-5180-476e-b452-7c8caef2ec76'	System	03 Dec 2020 16:19:44
User entered 'No (N)'	System	03 Dec 2020 16:19:44

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2020-12-03T10:19:36', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'af211713-5180-476e-b452-7c8caef2ec76'	System	03 Dec 2020 16:19:44
User entered 'No (N)'	System	03 Dec 2020 16:19:44

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-12-03T10:19:41', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'af211713-5180-476e-b452-7c8caef2ec76'	System	03 Dec 2020 16:19:44
User entered '03 Dec 2020 10:19:41'	System	03 Dec 2020 16:19:44

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-12-11T14:22:07', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c1111047-7497-46e4-b8d0-d69055c23a1b'	System	11 Dec 2020 20:22:30
User entered 'No (N)'	System	11 Dec 2020 20:22:30

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2020-12-11T14:22:21', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c1111047-7497-46e4-b8d0-d69055c23a1b'	System	11 Dec 2020 20:22:30
User entered 'No (N)'	System	11 Dec 2020 20:22:30

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-12-11T14:22:24', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'c1111047-7497-46e4-b8d0-d69055c23a1b' User entered '11 Dec 2020 14:22:24'	System	11 Dec 2020 20:22:30
	System	11 Dec 2020 20:22:30

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-12-17T03:38:48', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '80e25f2b-5df7-4df0-a7e0-4cc5d8be1d4d'	System	17 Dec 2020 09:38:58
User entered 'No (N)'	System	17 Dec 2020 09:38:58

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2020-12-17T03:38:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '80e25f2b-5df7-4df0-a7e0-4cc5d8be1d4d'	System	17 Dec 2020 09:38:58
User entered 'No (N)'	System	17 Dec 2020 09:38:58

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-12-17T03:38:56', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '80e25f2b-5df7-4df0-a7e0-4cc5d8be1d4d' User entered '17 Dec 2020 03:38:56'	System	17 Dec 2020 09:38:58
	System	17 Dec 2020 09:38:58

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-12-26T09:09:27', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ae9bd353-40ea-4f4a-bc60-e22ac3be072e'	System	26 Dec 2020 15:10:06
User entered 'Yes (Y)'	System	26 Dec 2020 15:10:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2020-12-26T09:09:31', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ae9bd353-40ea-4f4a-bc60-e22ac3be072e'	System	26 Dec 2020 15:10:06
User entered 'No (N)'	System	26 Dec 2020 15:10:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-12-26T09:09:41', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ae9bd353-40ea-4f4a-bc60-e22ac3be072e'	System	26 Dec 2020 15:10:06
User entered 'No (N)'	System	26 Dec 2020 15:10:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2020-12-26T09:09:52', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ae9bd353-40ea-4f4a-bc60-e22ac3be072e'	System	26 Dec 2020 15:10:06
User entered 'No (N)'	System	26 Dec 2020 15:10:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2020-12-26T09:10:04', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ae9bd353-40ea-4f4a-bc60-e22ac3be072e'	System	26 Dec 2020 15:10:06
User entered '26 Dec 2020 09:10:04'	System	26 Dec 2020 15:10:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-01-02T10:58:44', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a1f25e6e-80d6-4da4-95fb-0618371ce2b3'	System	02 Jan 2021 16:58:56
User entered 'No (N)'	System	02 Jan 2021 16:58:56

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-01-02T10:58:51', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a1f25e6e-80d6-4da4-95fb-0618371ce2b3'	System	02 Jan 2021 16:58:56
User entered 'No (N)'	System	02 Jan 2021 16:58:56

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-01-02T10:58:54', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a1f25e6e-80d6-4da4-95fb-0618371ce2b3'	System	02 Jan 2021 16:58:56
User entered '02 Jan 2021 10:58:54'	System	02 Jan 2021 16:58:56

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-01-10T10:16:58', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd157744f-10ab-4d83-90ae-c1af3252f229'	System	10 Jan 2021 16:17:09
User entered 'No (N)'	System	10 Jan 2021 16:17:09

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-01-10T10:17:02', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd157744f-10ab-4d83-90ae-c1af3252f229'	System	10 Jan 2021 16:17:09
User entered 'No (N)'	System	10 Jan 2021 16:17:09

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-01-10T10:17:06', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'd157744f-10ab-4d83-90ae-c1af3252f229'	System	10 Jan 2021 16:17:09
User entered '10 Jan 2021 10:17:06'	System	10 Jan 2021 16:17:09

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-01-15T18:42:40', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'aebf68f3-2a88-403f-b345-2bad5e8ac07a'	System	16 Jan 2021 00:42:49
User entered 'No (N)'	System	16 Jan 2021 00:42:49

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-01-15T18:42:43', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'aebf68f3-2a88-403f-b345-2bad5e8ac07a'	System	16 Jan 2021 00:42:49
User entered 'No (N)'	System	16 Jan 2021 00:42:49

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-01-15T18:42:46', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'aebf68f3-2a88-403f-b345-2bad5e8ac07a'	System	16 Jan 2021 00:42:49
User entered '15 Jan 2021 18:42:46'	System	16 Jan 2021 00:42:49

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-01-21T09:51:53', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ef0e2129-3d3a-4826-9562-0217bb544e15'	System	21 Jan 2021 15:52:06
User entered 'No (N)'	System	21 Jan 2021 15:52:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-01-21T09:51:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ef0e2129-3d3a-4826-9562-0217bb544e15'	System	21 Jan 2021 15:52:06
User entered 'No (N)'	System	21 Jan 2021 15:52:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-01-21T09:52:02', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'ef0e2129-3d3a-4826-9562-0217bb544e15'	System	21 Jan 2021 15:52:06
User entered '21 Jan 2021 09:52:02'	System	21 Jan 2021 15:52:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-01-31T12:56:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4cffffcd6-d06e-4641-b9b9-3ed4fe4f6820'	System	31 Jan 2021 18:57:08
User entered 'No (N)'	System	31 Jan 2021 18:57:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-01-31T12:57:02', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4cfffcd6-d06e-4641-b9b9-3ed4fe4f6820'	System	31 Jan 2021 18:57:08
User entered 'No (N)'	System	31 Jan 2021 18:57:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-01-31T12:57:06', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '4cffffcd6-d06e-4641-b9b9-3ed4fe4f6820'	System	31 Jan 2021 18:57:08
User entered '31 Jan 2021 12:57:06'	System	31 Jan 2021 18:57:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-02-07T14:48:55', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '39c268e9-f907-4164-83de-296a54f5650d'	System	07 Feb 2021 20:49:06
User entered 'No (N)'	System	07 Feb 2021 20:49:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-02-07T14:48:58', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '39c268e9-f907-4164-83de-296a54f5650d'	System	07 Feb 2021 20:49:06
User entered 'No (N)'	System	07 Feb 2021 20:49:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-02-07T14:49:01', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '39c268e9-f907-4164-83de-296a54f5650d'	System	07 Feb 2021 20:49:06
User entered '07 Feb 2021 14:49:01'	System	07 Feb 2021 20:49:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-02-14T07:45:45', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e19bc38b-d07b-45a5-8787-f544e7eae7aa'	System	14 Feb 2021 13:45:57
User entered 'No (N)'	System	14 Feb 2021 13:45:57

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-02-14T07:45:48', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e19bc38b-d07b-45a5-8787-f544e7eae7aa'	System	14 Feb 2021 13:45:57
User entered 'No (N)'	System	14 Feb 2021 13:45:57

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-02-14T07:45:52', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'e19bc38b-d07b-45a5-8787-f544e7eae7aa'	System	14 Feb 2021 13:45:57
User entered '14 Feb 2021 07:45:52'	System	14 Feb 2021 13:45:57

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-02-21T09:40:52', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1ebd5857-ce74-4f2b-a923-b0a102cfe04d'	System	21 Feb 2021 15:41:03
User entered 'No (N)'	System	21 Feb 2021 15:41:03

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-02-21T09:40:55', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1ebd5857-ce74-4f2b-a923-b0a102cfe04d'	System	21 Feb 2021 15:41:03
User entered 'No (N)'	System	21 Feb 2021 15:41:03

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-02-21T09:40:59', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '1ebd5857-ce74-4f2b-a923-b0a102cfe04d'	System	21 Feb 2021 15:41:03
User entered '21 Feb 2021 09:40:59'	System	21 Feb 2021 15:41:03

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-02-28T13:33:50-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a78ae92a-d4ff-4a73-8e76-76100c34d5ad'	System	28 Feb 2021 19:34:02
User entered 'No (N)'	System	28 Feb 2021 19:34:02

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-02-28T13:33:54-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a78ae92a-d4ff-4a73-8e76-76100c34d5ad'	System	28 Feb 2021 19:34:02
User entered 'No (N)'	System	28 Feb 2021 19:34:02

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-02-28T13:33:58-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'a78ae92a-d4ff-4a73-8e76-76100c34d5ad' User entered '28 Feb 2021 13:33:58'	System	28 Feb 2021 19:34:02

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-03-04T05:00:50-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '6c72d36a-8c06-403b-87cf-73186b38a31e'	System	04 Mar 2021 11:01:08
User entered 'No (N)'	System	04 Mar 2021 11:01:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-03-04T05:00:57-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '6c72d36a-8c06-403b-87cf-73186b38a31e'	System	04 Mar 2021 11:01:08
User entered 'No (N)'	System	04 Mar 2021 11:01:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-03-04T05:01:02-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '6c72d36a-8c06-403b-87cf-73186b38a31e' User entered '04 Mar 2021 05:01:02'	System	04 Mar 2021 11:01:08
	System	04 Mar 2021 11:01:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-03-11T14:50:16-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '6d668556-7b9d-4f26-9e45-e245d60d1aa3'	System	11 Mar 2021 20:50:32
User entered 'No (N)'	System	11 Mar 2021 20:50:32

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-03-11T14:50:19-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '6d668556-7b9d-4f26-9e45-e245d60d1aa3'	System	11 Mar 2021 20:50:32
User entered 'No (N)'	System	11 Mar 2021 20:50:32

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-03-11T14:50:23-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '6d668556-7b9d-4f26-9e45-e245d60d1aa3'	System	11 Mar 2021 20:50:32
User entered '11 Mar 2021 14:50:23'	System	11 Mar 2021 20:50:32

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-03-18T19:58:31-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '27cfc31d-2a1a-47c1-972b-e81f362116a1' User entered 'No (N)'	System	19 Mar 2021 00:58:42
	System	19 Mar 2021 00:58:42

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-03-18T19:58:35-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '27cfc31d-2a1a-47c1-972b-e81f362116a1'	System	19 Mar 2021 00:58:42
User entered 'No (N)'	System	19 Mar 2021 00:58:42

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-03-18T19:58:40-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '27cfc31d-2a1a-47c1-972b-e81f362116a1' User entered '18 Mar 2021 19:58:40'	System	19 Mar 2021 00:58:42
	System	19 Mar 2021 00:58:42

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-03-26T09:41:57-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '62cd5c75-a1c0-4ebe-9c2a-0f08237e7480'	System	26 Mar 2021 14:42:07
User entered 'No (N)'	System	26 Mar 2021 14:42:07

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-03-26T09:42:00-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '62cd5c75-a1c0-4ebe-9c2a-0f08237e7480'	System	26 Mar 2021 14:42:07
User entered 'No (N)'	System	26 Mar 2021 14:42:07

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-03-26T09:42:04-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '62cd5c75-a1c0-4ebe-9c2a-0f08237e7480' User entered '26 Mar 2021 09:42:04'	System	26 Mar 2021 14:42:07
	System	26 Mar 2021 14:42:07

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-04-01T17:51:55-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '297d0bec-9eb4-4738-a5c5-db2c9ff4a38d'	System	01 Apr 2021 22:52:06
User entered 'No (N)'	System	01 Apr 2021 22:52:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-04-01T17:51:57-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '297d0bec-9eb4-4738-a5c5-db2c9ff4a38d'	System	01 Apr 2021 22:52:06
User entered 'No (N)'	System	01 Apr 2021 22:52:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-04-01T17:52:01-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '297d0bec-9eb4-4738-a5c5-db2c9ff4a38d'	System	01 Apr 2021 22:52:06
User entered '01 Apr 2021 17:52:01'	System	01 Apr 2021 22:52:06

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-04-10T19:56:35-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '2906071e-a121-4398-a549-bc9dc752ed5d' User entered 'No (N)'	System	11 Apr 2021 00:56:46
	System	11 Apr 2021 00:56:46

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-04-10T19:56:39-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '2906071e-a121-4398-a549-bc9dc752ed5d'	System	11 Apr 2021 00:56:46
User entered 'No (N)'	System	11 Apr 2021 00:56:46

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-04-10T19:56:43-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '2906071e-a121-4398-a549-bc9dc752ed5d'	System	11 Apr 2021 00:56:46
User entered '10 Apr 2021 19:56:43'	System	11 Apr 2021 00:56:46

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-04-15T06:08:56-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8a8c2d9b-4468-4671-a7c8-593b87e0ead2' User entered 'No (N)'	System	15 Apr 2021 11:09:08
	System	15 Apr 2021 11:09:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-04-15T06:09:00-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8a8c2d9b-4468-4671-a7c8-593b87e0ead2'	System	15 Apr 2021 11:09:08
User entered 'No (N)'	System	15 Apr 2021 11:09:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-04-15T06:09:03-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '8a8c2d9b-4468-4671-a7c8-593b87e0ead2' User entered '15 Apr 2021 06:09:03'	System	15 Apr 2021 11:09:08
	System	15 Apr 2021 11:09:08

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-04-22T12:02:12-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '33694f2d-d6a4-4d69-8e51-e4d8a24e5f44'	System	22 Apr 2021 17:03:54
User entered 'No (N)'	System	22 Apr 2021 17:03:54

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-04-22T12:02:14-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '33694f2d-d6a4-4d69-8e51-e4d8a24e5f44'	System	22 Apr 2021 17:03:54
User entered 'No (N)'	System	22 Apr 2021 17:03:54

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-04-22T12:02:24-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '33694f2d-d6a4-4d69-8e51-e4d8a24e5f44'	System	22 Apr 2021 17:03:54
User entered '22 Apr 2021 12:02:24'	System	22 Apr 2021 17:03:54

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[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 (301dbbfd36453712)', Time: '2021-04-29T04:47:31-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f0cdd9d5-2d4c-4142-8854-7e49f86780df' User entered 'No (N)'	System	29 Apr 2021 09:47:57

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

Have you been exposed to someone with 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 (301dbbfd36453712)', Time: '2021-04-29T04:47:35-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f0cdd9d5-2d4c-4142-8854-7e49f86780df'	System	29 Apr 2021 09:47:57
User entered 'No (N)'	System	29 Apr 2021 09:47:57

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-04-29T04:47:39-05:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: 'f0cdd9d5-2d4c-4142-8854-7e49f86780df'	System	29 Apr 2021 09:47:57
User entered '29 Apr 2021 04:47:39'	System	29 Apr 2021 09:47:57

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:18:23

US3812257

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:37:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:23
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:18:23

US3812257

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:37:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-02-28T13:35:16-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '51e28748-69b6-448a-afee-1559ff3dc0ce'	System	28 Feb 2021 19:35:22
User entered 'No (N)'	System	28 Feb 2021 19:35:22

US3812257

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:37:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (301dbbfd36453712)', Time: '2021-02-28T13:35:19-06:00', User OID: 'PatientReportedOutcome (US3812257)', ODM File OID: '51e28748-69b6-448a-afee-1559ff3dc0ce' User entered '28 Feb 2021 13:35:19'	System	28 Feb 2021 19:35:22
	System	28 Feb 2021 19:35:22

US3812257

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Nov 2020 15:54:22

US3812257

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '17 Nov 2020'	Karen Knapp (b) (4)	17 Nov 2020 15:54:22

US3812257

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	17 Nov 2020 15:54:22

US3812257

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	17 Nov 2020 15:54:22

US3812257

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Nov 2020 15:54:27

US3812257

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:34:34
User entered 'I'	System	17 Nov 2020 15:54:27

US3812257

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:59:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	19 Dec 2020 17:26:19

US3812257

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:59:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '19 Dec 2020'	Karen Knapp (b) (4)	19 Dec 2020 17:26:19

US3812257

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:59:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	19 Dec 2020 17:26:19

US3812257

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:59:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	19 Dec 2020 17:26:19

US3812257

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:59:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	19 Dec 2020 17:26:23

US3812257

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:59:35
User entered 'I'	System	19 Dec 2020 17:26:23

US3812257

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:08:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Jan 2021 20:24:15

US3812257

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:08:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '21 Jan 2021'	Karen Knapp (b) (4)	21 Jan 2021 20:24:15

US3812257

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:08:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	21 Jan 2021 20:24:15

US3812257

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:08:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	21 Jan 2021 20:24:15

US3812257

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:08:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Jan 2021 20:24:20

US3812257

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:08:46
User entered 'I'	System	21 Jan 2021 20:24:20

US3812257

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:05:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	19 Feb 2021 22:28:43

US3812257

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:05:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '19 Feb 2021'	Karen Knapp (b) (4)	19 Feb 2021 22:28:43

US3812257

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:05:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	19 Feb 2021 22:28:43

US3812257

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:05:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	19 Feb 2021 22:28:43

US3812257

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:05:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	19 Feb 2021 22:28:51

US3812257

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:05:22
User entered '1'	System	19 Feb 2021 22:28:51

US3812257

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:28

US3812257

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:28

US3812257

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:28

US3812257

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered 'VISIT4'	System	09 Mar 2021 15:28:28

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered 'Yes (Y)'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '08 Mar 2021'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '15:16'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered '08 Mar 2021 15:16'	System	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '98.0' F	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered 'Oral (Oral)'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered empty.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '68'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered 'bpm'	System	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '18'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered 'breaths/min'	System	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '138'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered 'mmHg'	System	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:19
User entered '90'	Lyly Dang (b) (4) (b) (4)	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered 'mmHg'	System	06 Apr 2021 00:49:09

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50

US3812257

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50

US3812257

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:30

US3812257

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:30

US3812257

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:40

US3812257

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:40

US3812257

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '15:30'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:40

US3812257

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered '08 Mar 2021 15:30'	System	09 Mar 2021 15:28:40

US3812257

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Mar 2021 15:28:45

US3812257

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:50
User entered 'I'	System	09 Mar 2021 15:28:45

US3812257

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:01:37

US3812257

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '26 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:01:37

US3812257

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:01:37

US3812257

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:01:37

US3812257

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:02:58

US3812257

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 15:02:58

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:40:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Aug 2020'	Lyly Dang (b) (4)	04 Sep 2020 22:47:43

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:40:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '08:20'	Lyly Dang (b) (4)	04 Sep 2020 22:47:43

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:40:58
User entered '25 Aug 2020 08:20'	System	04 Sep 2020 22:47:43

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:40:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Lyly Dang (b) (4)	04 Sep 2020 22:47:43

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:40:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Lyly Dang (b) (4)	04 Sep 2020 22:47:43

US3812257

Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:37:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:41:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	30 Dec 2020 23:57:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	30 Dec 2020 23:55:01
User entered 'No (N)'	Karen Knapp (b) (4)	18 Oct 2020 13:08:53

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:08:55

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '16:45'	Breanna Galibert (b) (4)	31 Dec 2020 15:08:55

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:20
User entered '30 Dec 2020 16:45'	System	31 Dec 2020 15:08:55

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4)	31 Dec 2020 15:08:55

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:37:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:08:55

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '23 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Per CDM: It appears Assessment Not Done is checked but data is present. Please review Lines 1-7 and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 09:36:45
Query 'Per CDM: It appears Assessment Not Done is checked but data is present. Please review Lines 1-7 and update accordingly. ' answered with 'UPDATED' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	18 Jan 2021 20:07:52
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	18 Jan 2021 20:07:38
User opened query 'Per CDM: It appears Assessment Not Done is checked but data is present. Please review Lines 1-7 and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:35:26
User entered '1'	Breanna Galibert (b) (4) (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1-7. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 09:36:50
Query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1-7. If not collected, please consider recording these as NOT DONE' answered with 'UPDATED' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	18 Jan 2021 20:07:58
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	18 Jan 2021 20:07:38
User opened query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1-7. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:35:43
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:22

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '24 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '25 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:09:47

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '26 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '27 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:18

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '28 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:34

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 7 (Day 7)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '29 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0' reason for change: Per Query Resolution	Breanna Galibert (b) (4)	18 Jan 2021 20:07:38
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	18 Jan 2021 20:07:38
User entered empty.	System	31 Dec 2020 15:10:49

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	18 Jan 2021 20:07:38
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:10:49

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 8 (Day 8)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	31 Dec 2020 15:11:08

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.1' F	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:08

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 9 (Day 9)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '31 Dec 2020'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97.8' F	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:50:38

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 10 (Day 10)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '01 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:51:01

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97.7' F	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:01

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 11 (Day 11)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '02 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '96.7' F	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:24

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 12 (Day 12)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '03 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.2' F	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

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Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:51:51

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 13 (Day 13)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '04 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.3' F	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:09

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 14 (Day 14)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '05 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '99'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97.9' F	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:29

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 15 (Day 15)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '06 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.2' F	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:52:48

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 16 (Day 16)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '07 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.3' F	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:06

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 17 (Day 17)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '08 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '99'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.5' F	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:25

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Day 18 (Day 18)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User entered '%'	System	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.3' F	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:37:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'None (None)'	Breanna Galibert (b) (4)	11 Jan 2021 19:53:41

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

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 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[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 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

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Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

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Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

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Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[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 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:11:26

US3812257

Folder: Covid-19 Assessment 30 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:37:16

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:42:35
User entered '0'	System	31 Dec 2020 15:11:26

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '01 Jan 2021'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '03 Jan 2021'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '05 Jan 2021'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '07 Jan 2021'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 14 (Day 14)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 21 (Day 21)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:37:16

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User accepted default value 'Day 28 (Day 28)'	Breanna Galibert (b) (4) (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:37:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 19:54:22

US3812257

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:47

US3812257

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:47

US3812257

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[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 11:36:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	31 Dec 2020 15:11:47

US3812257

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:47
User entered 'SICKD1'	System	31 Dec 2020 15:11:47

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '17:12'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User entered '30 Dec 2020 17:12'	System	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '69.1' in	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19
DataPoint set to visible.	System	31 Dec 2020 15:11:47

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '360.6' lb	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19
DataPoint set to visible.	System	31 Dec 2020 15:11:47

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '98.1' F	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '94'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User entered 'bpm'	System	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '16'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User entered 'breaths/min'	System	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '146'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User entered 'mmHg'	System	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '80'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58
User entered 'mmHg'	System	31 Dec 2020 15:12:19

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58

US3812257

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:37:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:36:58

US3812257

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:25

US3812257

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:25

US3812257

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:37:16

[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 11:37:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:29

US3812257

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:37:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:37:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:12:29

US3812257

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

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	16 Jan 2021 19:44:33

US3812257

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

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:53:58
User entered '15 Jan 2021'	Heather Cherniawski	16 Jan 2021 19:44:33
	(b) (4)	

US3812257

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

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Clinic (Clinic)'	Heather Cherniawski	16 Jan 2021 19:44:33

US3812257

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

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 19:44:33

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '15 Jan 2021'	Heather Cherniawski (b) (4)	16 Jan 2021 19:44:53

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '0'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:51

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	16 Jan 2021 19:44:53

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:51

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '15 Jan 2021'	Heather Cherniawski	16 Jan 2021 19:44:53

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Placebo (Placebo)'	Heather Cherniawski	16 Jan 2021 19:44:53

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 12:49:25
User entered 'Placebo (Placebo)'	Heather Cherniawski	16 Jan 2021 19:44:53
	(b) (4)	

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 12:49:25
User entered 'Placebo (Placebo)'	Heather Cherniawski	16 Jan 2021 19:44:53
	(b) (4)	

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	16 Jan 2021 19:44:53

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '1'	System	16 Jan 2021 19:44:53

US3812257

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

Form: Unblinding

Generated On: 12 Aug 2021 13:37:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '1'	System	16 Jan 2021 19:44:53

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '69.1' in	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '350.8' lb reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:24
User entered '360.8' lb reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 15:56:08
User entered '360.6' lb	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '51.76228'	System	01 Feb 2021 15:56:24
User entered '53.23783'	System	01 Feb 2021 15:56:08
User entered '53.20832'	System	16 Jan 2021 19:47:21
DataPoint set to visible.	System	16 Jan 2021 19:44:53

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '69.1' in	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '350.8' lb reason for change: Data Entry Error	(b) (4)	
User entered '360.8' lb reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 15:56:24
	(b) (4)	
User entered '360.8' lb reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 15:56:08
	(b) (4)	
User entered '360.6' lb	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '51.76228'	System	01 Feb 2021 15:56:24
User entered '53.23783'	System	01 Feb 2021 15:56:08
User entered '53.20832'	System	16 Jan 2021 19:47:21
DataPoint set to visible.	System	16 Jan 2021 19:44:53

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	01 Feb 2021 15:56:08
User entered '01 Feb 2021' reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 15:56:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	01 Feb 2021 15:53:58
User entered '15 Jan 2021'	System	01 Feb 2021 15:53:58
	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	01 Feb 2021 16:22:06
User entered '08:37' reason for change: Data Entry Error	System	01 Feb 2021 16:22:06
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	Heather Cherniawski	01 Feb 2021 15:57:09
User entered '14:02'	(b) (4)	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '01 Feb 2021 08:37'	System	01 Feb 2021 16:22:06
User entered '01 Feb 2021 14:02'	System	01 Feb 2021 15:56:08
User entered '15 Jan 2021 14:02'	System	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '97.1' F	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Oral (Oral)'	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '70' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:08
User entered '80'	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'bpm'	System	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '18' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:08
User entered '15'	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'breaths/min'	System	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '132' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:08
User entered '122'	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '80' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:08
User entered '78'	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

US3812257

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '69.1' in	Heather Cherniawski	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '350.8' lb reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:24
User entered '360.8' lb reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 15:56:08
User entered '360.6' lb	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

US3812257

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:37:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '51.76228'	System	01 Feb 2021 15:56:24
User entered '53.23783'	System	01 Feb 2021 15:56:08
User entered '53.20832'	System	16 Jan 2021 19:47:21
DataPoint set to visible.	System	16 Jan 2021 19:44:53

US3812257

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4)	01 Feb 2021 15:56:31
User entered 'Yes (Y)' reason for change: Data Entry Error	System	01 Feb 2021 15:56:31
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	Heather Cherniawski	01 Feb 2021 15:56:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Feb 2021 15:56:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Jan 2021 19:47:31
User entered 'No (N)' reason for change: Data Entry Error	System	16 Jan 2021 19:47:31
User opened query 'Data is required. Please complete.' (Site from System).	Heather Cherniawski	16 Jan 2021 19:47:31
User entered empty.	(b) (4)	16 Jan 2021 19:47:21
	System	16 Jan 2021 19:47:21
	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:56:08
User entered empty.	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
	System	01 Feb 2021 16:22:06
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	01 Feb 2021 15:56:08
User entered '10:08' reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 15:56:08
	(b) (4)	
User entered empty.	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '01 Feb 2021 10:08'	System	01 Feb 2021 15:56:08
User entered empty.	System	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 16:22:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Feb 2021 16:22:06
User entered '97.2' F reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 16:22:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 15:56:31
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 16:22:06
User entered empty.	Heather Cherniawski	16 Jan 2021 19:47:21
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 16:22:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Feb 2021 16:22:06
User entered '66' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 16:22:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 15:56:31
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'bpm'	System	01 Feb 2021 16:22:06
User entered empty.	System	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 16:22:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Feb 2021 16:22:06
User entered '14' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 16:22:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 15:56:31
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'breaths/min'	System	01 Feb 2021 16:22:06
User entered empty.	System	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 16:22:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Feb 2021 16:22:06
User entered '138' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 16:22:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 15:56:31
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	01 Feb 2021 16:22:06
User entered empty.	System	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 16:22:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Feb 2021 16:22:06
User entered '90' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 16:22:06
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 15:56:31
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:47:21

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	01 Feb 2021 16:22:06
User entered empty.	System	16 Jan 2021 19:47:21

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:47:41

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Heather Cherniawski	16 Jan 2021 19:47:41

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:57:09
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Was study treatment given? = Yes, however If No, reason not given is provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	01 Feb 2021 15:57:33
User opened query 'Was study treatment given? = Yes, however If No, reason not given is provided. Please review and reconcile.' (Site from System).	Heather Cherniawski	01 Feb 2021 15:57:33
User entered 'Other (OTHER)'	(b) (4)	
	System	01 Feb 2021 15:57:09
	Heather Cherniawski	16 Jan 2021 19:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

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)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'SUBJECT IS DELAYED CURRENTLY BEING TREATED FOR ACUTE EAR INFECTION. PER SUBJECT, STILL TAKING ANTIBIOTICS'	Heather Cherniawski (b) (4)	16 Jan 2021 19:49:05

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mRNA-1273'	System	01 Feb 2021 15:57:09
User entered empty.	System	16 Jan 2021 19:49:05
DataPoint set to visible.	System	16 Jan 2021 19:44:53

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:57:09
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:38' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:57:09
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '01 Feb 2021 09:38'	System	01 Feb 2021 15:57:09
User entered empty.	System	16 Jan 2021 19:49:05

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:57:09
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:05
	(b) (4)	

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'ONCE'	System	01 Feb 2021 15:57:09
User entered empty.	System	16 Jan 2021 19:49:05

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

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 15:57:09
User entered empty.	System	16 Jan 2021 19:49:05

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:58:01
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:49:11
	(b) (4)	

US3812257

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:58:01
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:11
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:05' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:58:01
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:11
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:37:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '01 Feb 2021 09:05'	System	01 Feb 2021 15:58:01
User entered empty.	System	16 Jan 2021 19:49:11

US3812257

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:37:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:58:16
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:49:16
	(b) (4)	

US3812257

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:37:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	01 Feb 2021 15:58:36
User entered '01 Feb 2021' reason for change: Data Entry Error	System	01 Feb 2021 15:58:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Heather Cherniawski	01 Feb 2021 15:58:16
User entered '01 Feb ' (non-conformant).	(b) (4)	01 Feb 2021 15:58:16
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:16
	(b) (4)	

US3812257

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:37:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '09:10' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 15:58:16
User entered empty.	Heather Cherniawski	16 Jan 2021 19:49:16
	(b) (4)	

US3812257

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:37:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '01 Feb 2021 09:10'	System	01 Feb 2021 15:58:36
User entered '01 Feb 09:10' (non-conformant).	System	01 Feb 2021 15:58:16
User entered empty.	System	16 Jan 2021 19:49:16

US3812257

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

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Cherniawski	08 Feb 2021 21:16:56
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski	16 Jan 2021 19:45:35
User entered 'Yes (Y)'	Heather Cherniawski	16 Jan 2021 19:45:00

US3812257

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

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '1'	System	08 Feb 2021 21:16:56
User entered empty.	System	16 Jan 2021 19:45:35
User entered '1'	System	16 Jan 2021 19:45:00

US3812257

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Feb 2021 21:21:31

US3812257

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered '8 Feb 2021'	Karen Knapp (b) (4)	08 Feb 2021 21:21:31

US3812257

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	08 Feb 2021 21:21:31

US3812257

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Karen Knapp (b) (4)	08 Feb 2021 21:21:31

US3812257

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered 'Yes (Y)'	Karen Knapp (b) (4)	08 Feb 2021 21:21:36

US3812257

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'I'	System	08 Feb 2021 21:21:36

US3812257

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '1'	System	08 Feb 2021 21:21:36
DataPoint set to visible.	System	08 Feb 2021 21:21:36

US3812257

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:26:59

US3812257

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:26:59

US3812257

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:26:59

US3812257

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:37:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'OLD29'	System	09 Mar 2021 15:26:59

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '15:16'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '08 Mar 2021 15:16'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '98.0' F	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '68'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'bpm'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '18'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'breaths/min'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '136'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '90'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:37:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '16:11'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '08 Mar 2021 16:11'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '97.9' F	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '72'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'bpm'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '18'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'breaths/min'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '134'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '88'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:37:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mmHg'	System	09 Mar 2021 15:28:18

US3812257

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:13

US3812257

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:37:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:13

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

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)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'mRNA-1273'	System	09 Mar 2021 15:27:23
DataPoint set to visible.	System	08 Feb 2021 21:21:36

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '08 Mar 2021'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '15:39'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered '08 Mar 2021 15:39'	System	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Right Arm (RIGHT ARM)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'ONCE'	System	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:37:16

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 15:27:23

US3812257

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	09 Mar 2021 15:27:25

US3812257

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'I'	System	09 Mar 2021 15:27:25

US3812257

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:33

US3812257

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered '15 Mar 2021'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:33

US3812257

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:33

US3812257

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:37:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered empty.	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:33

US3812257

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	15 Mar 2021 20:42:37

US3812257

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:37:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:15:06
User entered 'I'	System	15 Mar 2021 20:42:37

US3812257

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:37:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:14:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	31 Dec 2020 15:12:46
User entered 'No (N)'	Karen Knapp (b) (4)	13 Sep 2020 12:21:31

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media, LLT: Bilateral otitis media - version MedDRA\\23.0.	Coder Import (b) (4)	31 Dec 2020 15:20:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Dec 2020 15:20:35
Data point term sent to Coder	System	31 Dec 2020 15:20:15
User entered 'bilateral otitis media'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User entered empty.	System	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 16:23:36
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	31 Dec 2020 15:19:19
	Breanna Galibert (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 16:23:36
User entered empty.	Heather Cherniawski (b) (4)	31 Dec 2020 15:19:19
	Breanna Galibert (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User entered empty.	System	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'I'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	01 Feb 2021 16:23:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:19:19

US3812257

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User entered '0'	System	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04
User entered 'I'	System	31 Dec 2020 15:19:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:37:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:22:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing disorders NEC, PT: Diplacusis, LLT: Diplacusis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 19:44:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Jan 2021 19:44:53
Data point term sent to Coder	System	16 Jan 2021 19:43:49
User entered 'DIPLACUSIS'	Heather Cherniawski	16 Jan 2021 19:43:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Yes (Y)'	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '30 Dec 2020'	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User entered empty.	System	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)' reason for change: New Information	Maureen Dempsey (b) (4)	16 Feb 2021 19:36:07
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '15 Jan 2021' reason for change: New Information	Maureen Dempsey (b) (4)	16 Feb 2021 19:36:07
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User entered empty.	System	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Not Related (NOT RELATED)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Not Related (NOT RELATED)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Not Applicable (NOT APPLICABLE)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'I'	Heather Cherniawski	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered '0'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Maureen Dempsey (b) (4)	16 Feb 2021 19:36:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered empty.	Heather Cherniawski (b) (4)	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User entered '0'	System	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59
User entered '1'	System	16 Jan 2021 19:43:21

US3812257

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:37:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:59

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User closed query 'Per CDM: According to CCGs (v5, pgs. 47-49), AE term MUST be entered as COVID-19. Please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 14:17:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 19:41:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 19:41:07
Data point term sent to Coder	System	04 Mar 2021 19:40:35
Query 'Per CDM: According to CCGs (v5, pgs. 47-49), AE term MUST be entered as COVID-19. Please confirm and update where necessary. Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	04 Mar 2021 19:40:31
Signature has been broken.	Angie Kean (b) (4) (b) (4)	04 Mar 2021 19:40:26
User entered 'COVID-19 INFECTION' reason for change: Per Query Resolution	Angie Kean (b) (4) (b) (4)	04 Mar 2021 19:40:26
User opened query 'Per CDM: According to CCGs (v5, pgs. 47-49), AE term MUST be entered as COVID-19. Please confirm and update where necessary. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:23:37
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	23 Feb 2021 22:00:11
Data point term sent to Coder	System	23 Feb 2021 00:53:12
User entered 'positive pcr covid swab'	Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '25 Aug 2020'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM: Site response is noted, however, according to CCGs (v5, pg. 49), the start time must be completed if AE occurred within 24 hours of dosing. Visit 1 Exposure occurred on 25Aug at 10:08. Please confirm and update where necessary, otherwise, clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 14:17:21
Query 'Per CDM: Site response is noted, however, according to CCGs (v5, pg. 49), the start time must be completed if AE occurred within 24 hours of dosing. Visit 1 Exposure occurred on 25Aug at 10:08. Please confirm and update where necessary, otherwise, clarify. Thank you.' answered with 'UNKNOWN.' (Site from DM).	Angie Kean (b) (4) (b) (4)	04 Mar 2021 19:40:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 11:58:46
User opened query 'Per CDM: Site response is noted, however, according to CCGs (v5, pg. 49), the start time must be completed if AE occurred within 24 hours of dosing. Visit 1 Exposure occurred on 25Aug at 10:08. Please confirm and update where necessary, otherwise, clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:29:46
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	23 Feb 2021 22:00:11
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:54
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:52:34
User entered empty.	Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '11 Jan 2021'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 20:23:59
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	Angie Kean (b) (4)	23 Feb 2021 00:52:59
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Feb 2021 00:52:34
User entered empty.	Angie Kean (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered '0'	(b) (4) Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 20:30:53
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'subject was asymptomatic, dosing discontinue due to positive PCR swab per protocol. ' (Site from System).	Angie Kean (b) (4)	23 Feb 2021 00:54:50
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Feb 2021 00:52:34
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Angie Kean (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

None

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered 'I'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	23 Feb 2021 22:00:11
User entered empty.	(b) (4)	
	Angie Kean (b) (4)	23 Feb 2021 00:52:34
	(b) (4)	

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:37:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Feb 2021 00:52:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of hand - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 15:05:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 May 2021 15:05:18
Data point term sent to Coder	System	03 May 2021 15:04:22
User entered 'laceration right hand'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '21 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 15:03:34

US3812257

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:37:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 15:03:34

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:37:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:14:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:32:23

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Oct 2020 21:00:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:00:45
Data point term sent to Coder Coding entries removed.	System Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:08:26 29 Oct 2020 14:07:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:34:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:34:33
Data point term sent to Coder User entered 'ALLOPURINOL'	System Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:33:43 05 Sep 2020 16:33:30

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
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) (4), (b) (6)	23 Nov 2020 14:10:51
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 to no' (Site from DM).	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:07:38
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:07:31
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)	01 Oct 2020 18:49:34
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	(b) (4), (b) (6)	01 Oct 2020 18:49:29
' canceled (Site from DM).		
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.	(b) (4), (b) (6)	01 Oct 2020 18:49:20
' (Site from DM).		
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:33:30

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:10:54
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated with location' (Site from DM).	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:07:45
User entered 'gout bilateral feet and knees' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	29 Oct 2020 14:07:31
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:59:09
Query "'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. 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.' canceled (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:59:05
User opened query "'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. 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)	26 Oct 2020 19:55:45
User entered 'GOUT'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:33:30

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '300'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'twice daily (BID)'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Aug 2012'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:33:30
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Sep 2020 16:33:30

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:33:30

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:33:30

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:35:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:35:33
Data point term sent to Coder	System	05 Sep 2020 16:34:43
User entered 'FUROSEMIDE'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:34:29

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'HYPERTENSION'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '80'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Aug 2012'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:34:29
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:34:29

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:34:29

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:34:29

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:37:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:37:34
Data point term sent to Coder User entered 'AMLODIPINE'	System Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:36:45 05 Sep 2020 16:35:59

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'HYPERTENSION'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '5'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Jun 2005'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:35:59
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:35:59

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:35:59

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:35:59

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:38:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:38:34
Data point term sent to Coder User entered 'CARVEDILOL'	System Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:37:46 05 Sep 2020 16:36:56

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'HYPERTENSION'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '25'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Jun 2005'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:36:56
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:36:56

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:36:56

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:36:56

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:39:35
Data point term sent to Coder	System	05 Sep 2020 16:38:48
User entered 'ATORVASTATIN'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:38:09

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:38:09

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '40'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Aug 2012'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:38:09
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:38:09

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:38:09

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:38:09

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:40:36
Data point term sent to Coder User entered 'LOSARTAN'	System Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:39:49 05 Sep 2020 16:38:55

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'HYPERTENSION'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '25'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Aug 2012'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:38:55
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'No (N)'	(b) (4) Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:38:55

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:38:55

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:38:55

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:38:55

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Sep 2020 16:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:42:37
Data point term sent to Coder	System	05 Sep 2020 16:41:52
User entered 'POTASSIUM'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:41:00

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'POTASSIUM DEFICIENCY'	(b) (4) Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:41:00

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '20'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Other (OTHER)'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'MEQ'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH date incorrect. updated appropriately' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:11:03
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	Any Penly (b) (4)	30 Oct 2020 22:39:12
User entered 'UN Aug 2012'	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 05:42:37
	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:41:00
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:41:00

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:41:00

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:41:00

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 16:42:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 16:42:37
Data point term sent to Coder User entered 'ASPIRIN'	System Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:41:53 05 Sep 2020 16:41:42

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'CARDIAC HEALTH'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '81'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN Aug 2012'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:41:42
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:41:42

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:41:42

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:41:42

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 01:13:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 01:13:38
Data point term sent to Coder	System	05 Sep 2020 16:45:58
User entered 'ZYRTEC'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:45:01

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User entered 'SEASONAL/ENVIRONMENTAL ALLERGIES'	(b) (4) Angie Kean (b) (4) (b) (4)	05 Sep 2020 16:45:01

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '10'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'UN UNK 2010'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:45:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 16:45:42
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4)	05 Sep 2020 16:45:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 16:45:01
User entered empty.	Angie Kean (b) (4)	05 Sep 2020 16:45:01
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:45:01

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 16:45:01

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 16:45:01

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User closed query 'Per CDM: Please update "Name of Medication" to "Influenza Vaccine:. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 09:47:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 17:10:40
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 Jan 2021 17:10:40
Data point term sent to Coder	System	11 Jan 2021 17:10:16
Query 'Per CDM: Please update "Name of Medication" to "Influenza Vaccine:. Thank you. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	11 Jan 2021 17:09:20
Coding entries removed.	Angie Kean (b) (4) (b) (4)	11 Jan 2021 17:09:15
User entered 'influenza vaccine' reason for change: New Information	Angie Kean (b) (4) (b) (4)	11 Jan 2021 17:09:15
User opened query 'Per CDM: Please update "Name of Medication" to "Influenza Vaccine:. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:25:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Dec 2020 15:21:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Dec 2020 15:21:40
Data point term sent to Coder	System	31 Dec 2020 15:21:16
User entered 'flu vaccine'	Breanna Galibert (b) (4) (b) (4)	31 Dec 2020 15:20:25

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'flu prevention'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '1'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'dose'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '29 Oct 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '29 Oct 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:20:25
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 15:20:25

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 15:20:25

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 15:20:25

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Dec 2020 15:30:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Dec 2020 15:30:36
Data point term sent to Coder	System	31 Dec 2020 15:29:27
User entered 'amoxicillin'	Breanna Galibert (b) (4) (b) (4)	31 Dec 2020 15:28:47

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'bilateral otitis media'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '500'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Breanna Galibert (b) (4)	11 Jan 2021 19:54:43
Data Entry Error	(b) (4)	
User entered 'three times daily (TID)'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '30 Dec 2020'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 16:24:24
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '15 Jan 2021' reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 16:24:24
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Dec 2020 15:28:47
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Jan 2021 19:54:43
User entered '3'	System	31 Dec 2020 15:28:47

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Dec 2020 15:28:47

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Dec 2020 15:28:47

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Jan 2021 21:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:16:42
Data point term sent to Coder	System	11 Jan 2021 19:56:14
User entered 'PREDNISONE'	Breanna Galibert (b) (4) (b) (4)	11 Jan 2021 19:55:19

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'BILATERAL OTITIS MEDIA'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '20'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '01 Jan 2021'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 16:26:44
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered '06 Jan 2021' reason for change: Data Entry Error	Heather Cherniawski	01 Feb 2021 16:26:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Jan 2021 19:55:19
	(b) (4)	

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:55:19

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:55:19

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 19:55:19

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 15:58:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 15:58:22
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
Data point term sent to Coder	System	03 May 2021 15:04:22
User entered 'keflex'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'right hand laceration'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '500'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'twice daily (BID)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '21 Apr 2021'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered '0'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered empty.	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	03 May 2021 15:16:46
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 May 2021 15:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 15:04:16

US3812257

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:37:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 May 2021 15:04:16

US3812257

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:37:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:17
	(b) (4)	
User entered 'No (N)'	Karen Knapp (b) (4)	13 Sep 2020 12:21:39
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:37:16

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:44
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:22:24
User closed query 'Per CDM : The Subject Received first Dose on 25 Aug 2020. and not Received Second Dose on V2 Day 29(23 sep 2020) due to COVID-19. Kindly Review and update the Date of dosing discontinuation to 23 sep 2020 since the subject had not missed any follow up safety calls and continuing the study. else clarify. Thank You.' (Site from DM). Query 'Per CDM : The Subject Received first Dose on 25 Aug 2020. and not Received Second Dose on V2 Day 29(23 sep 2020) due to COVID-19. Kindly Review and update the Date of dosing discontinuation to 23 sep 2020 since the subject had not missed any follow up safety calls and continuing the study. else clarify. Thank You.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:19:01
Signature has been broken.	Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:41:23
User entered '23 Sep 2020' reason for change: Per Query Resolution	Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:41:19
User opened query 'Per CDM : The Subject Received first Dose on 25 Aug 2020. and not Received Second Dose on V2 Day 29(23 sep 2020) due to COVID-19. Kindly Review and update the Date of dosing discontinuation to 23 sep 2020 since the subject had not missed any follow up safety calls and continuing the study. else clarify. Thank You.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	22 Feb 2021 11:24:09
User entered '25 Aug 2020'	Larkin Wadsworth (b) (4) (b) (4) Lyly Dang (b) (4) (b) (4)	20 Feb 2021 23:39:40 05 Dec 2020 19:00:04

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:37:16

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:34:44
User closed query 'Per CDM : Primary reason for dosing discontinuation is Due to SARS-COV-2. However there no AE recorded in AE eCRF Page. Kindly review and update the data as Applicable. Thank You' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:18:50
Query 'Per CDM : Primary reason for dosing discontinuation is Due to SARS-COV-2. However there no AE recorded in AE eCRF Page. Kindly review and update the data as Applicable. Thank You' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 00:50:03
User opened query 'Per CDM : Primary reason for dosing discontinuation is Due to SARS-COV-2. However there no AE recorded in AE eCRF Page. Kindly review and update the data as Applicable. Thank You' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 11:11:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:39:40
User entered 'Due to SARS-COV-2 (COVID)'	Lyly Dang (b) (4) (b) (4)	05 Dec 2020 19:00:04

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:37:16

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 04:34:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:39:40
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 19:00:04