

US3442173 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:43:12

All time stamps listed in this document are displayed in GMT

US3442173

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

[Participant ID](#)

US3442173

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

US3442173

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 19:13:00

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Date of Informed Consent (<i>dd MMM yyyy</i>)	16 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 19:13:00

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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) 23 Feb 2021 19:13:00

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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) 23 Feb 2021 19:13:00

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Condition	PENICILLIN ALLERGY: HIVES RASH
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	HOT FLASHES
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	GALL BLADDER REMOVAL
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:00
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	201 lb
BMI (<i>xxx.x</i>)	33.51809 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Date of assessment (dd MMM yyyy) 16 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2017

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 19:13:00

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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

DISABILITY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 19:13:00

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 146431

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) 23 Feb 2021 19:13:01

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:00
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:33
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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) 23 Feb 2021 19:13:00

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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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 12:07 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 12:07

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) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	11:20 (24 HR)
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Collection date and time (derived)	16 SEP 2020 11:20
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:28	16 SEP 2020 11:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

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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: 11 Aug 2021 22:43:12

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:40

PC Open Date & Time

16 SEP 2020 12:27

PC Close Date & Time

16 SEP 2020 14:57

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

97.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	16 SEP 2020 17:24
PC Open Date & Time	16 SEP 2020 15:52
PC Close Date & Time	17 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

17 SEP 2020 18:09

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 19 SEP 2020 20:42

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 09:17

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

22 SEP 2020 12:04

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

16 SEP 2020 12:41

PC Open Date & Time

16 SEP 2020 12:27

PC Close Date & Time

16 SEP 2020 14:57

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

16 SEP 2020 17:25

PC Open Date & Time

16 SEP 2020 15:52

PC Close Date & Time

17 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

17 SEP 2020 18:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

18 SEP 2020 12:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

19 SEP 2020 20:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

20 SEP 2020 12:09

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

22 SEP 2020 09:17

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

22 SEP 2020 12:04

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 12:41
PC Open Date & Time	16 SEP 2020 12:27
PC Close Date & Time	16 SEP 2020 14:57

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 17:26
PC Open Date & Time	16 SEP 2020 15:52
PC Close Date & Time	17 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

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 ☒

PRODUCTION RELEASE (v12.003

63 of 2779

EAB) (1725)

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 2779

EAB) (1725)

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 20:43
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

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 ☒

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 12:09
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

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 ☒

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 09:18
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

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 ☒

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:04
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3442173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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

Visit date (dd MMM yyyy)	15 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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)	15 OCT 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:14
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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)	15 OCT 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:20
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3442173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 11:48 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 11:48

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

US3442173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

11:18 (24 HR)

Collection date and time (derived)

15 OCT 2020 11:18

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	15 OCT 2020 11:20
Nasopharyngeal Swab 2	No		

US3442173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 15 OCT 2020 12:21

PC Open Date & Time 15 OCT 2020 12:08

PC Close Date & Time 15 OCT 2020 14:38

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	15 OCT 2020 19:53
PC Open Date & Time	15 OCT 2020 15:33
PC Close Date & Time	16 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 18:01

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 13:52

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

97.2 °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

18 OCT 2020 16:42

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

19 OCT 2020 12:14

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

20 OCT 2020 18:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 15:01

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 12:19

PC Open Date & Time

15 OCT 2020 12:08

PC Close Date & Time

15 OCT 2020 14:38

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

15 OCT 2020 19:53

PC Open Date & Time

15 OCT 2020 15:33

PC Close Date & Time

16 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

16 OCT 2020 18:00

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

17 OCT 2020 13:53

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

18 OCT 2020 16:42

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

19 OCT 2020 12:14

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

20 OCT 2020 18:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

21 OCT 2020 15:02

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 12:19
PC Open Date & Time	15 OCT 2020 12:08
PC Close Date & Time	15 OCT 2020 14:38

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 19:54
PC Open Date & Time	15 OCT 2020 15:33
PC Close Date & Time	16 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 18:00
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

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 ☒

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 13:53
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 16:43
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

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)

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:15
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 18:11
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

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)

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US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 15:02
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3442173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

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.

US3442173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 NOV 2020

Collection time (00:00-23:59)

12:30 (24 HR)

Collection date and time (derived)

9 NOV 2020 12:30

US3442173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:01

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 11:43:31
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 17:06:33
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 75
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	01 DEC 2020 12:14:19
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 16:48:46
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 DEC 2020 09:54:10
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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	19 DEC 2020 17:00:31
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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	04 JAN 2021 12:12:42
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

11 JAN 2021 10:24:58

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 18:45:01
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 14:13:41
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

29 JAN 2021 13:12:58

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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	09 FEB 2021 08:11:47
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

22 FEB 2021 14:49:49

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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	01 MAR 2021 18:13:19
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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	12 MAR 2021 09:50:03
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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	23 MAR 2021 12:19:05
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 12:14:48

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

12 APR 2021 17:59:41

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

19 APR 2021 18:04:37

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

25 APR 2021 12:01:01

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

02 MAY 2021 12:00:29

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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21 JUN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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28 JUN 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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05 JUL 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 <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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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12 JUL 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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19 JUL 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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26 JUL 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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02 AUG 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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09 AUG 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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16 AUG 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

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23 AUG 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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30 AUG 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3442173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:43:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 18:13:42

US3442173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

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.

US3442173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

11:50 (24 HR)

Collection date and time (derived)

30 MAR 2021 11:50

US3442173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

Date of Contact	7 DEC 2020
Time of Contact	09:52
Date and Time of Contact (derived)	7 DEC 2020 09:52
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	4 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 type="radio"/>
	Mild	<input checked="" 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 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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 type="radio"/>
	Mild	<input checked="" 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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	5 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" 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 07 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 type="radio"/>
	Mild	<input checked="" 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 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	6 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 type="radio"/>
	Mild	<input checked="" 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 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" 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 07 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	7 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.8 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 type="radio"/>
	Mild	<input checked="" 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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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" 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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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 (5)

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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)

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	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	8 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 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 type="radio"/>
	Mild	<input checked="" 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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	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 (5)

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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"/>

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Form: Symptom Log (6)

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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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Form: Symptom Log (6)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	9 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.0 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 type="radio"/>
	Mild	<input checked="" 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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	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 type="radio"/>
	Mild	<input checked="" 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)

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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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.7 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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	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 (7)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 13 Apr 2021 15:28:16

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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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Form: Symptom Log (8)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 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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	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 (8)

Data signed: (b) (4) 13 Apr 2021 15:28:16

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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"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.7 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 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.8 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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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"/>

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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	18 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.5 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 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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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US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 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 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		403 of 2779
EAB) (1725)		

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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"/>

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

Date of Visit 7 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 7 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 12 DEC 2020

End Date 15 DEC 2020

Oxygen Saturation 92 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

PRODUCTION RELEASE (v12.003

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US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	9 DEC 2020
Day 5	Yes	11 DEC 2020
Day 7	Yes	13 DEC 2020
Day 9	Yes	15 DEC 2020
Day 14	Yes	20 DEC 2020
Day 21	Yes	27 DEC 2020
Day 28	Yes	05 JAN 2021

US3442173

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 DEC 2020
Time of assessment (00:00-23:59)	13:38 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 13:38
Height (xxx.x)	65.0 in
Weight (xxx.x)	203.0 lb
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3442173

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

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

US3442173

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 DEC 2020

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 JAN 2021
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 13:39
Height (xxx.x)	65.0 in
Weight (xxx.x)	202.8 lb
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3442173

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

5 JAN 2021

US3442173

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3442173

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

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

US3442173

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Height	
Weight	
BMI (xxx.x)	

US3442173

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 09:36
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3442173

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 11:18
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3442173

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3442173

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 10:38 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 10:38

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

US3442173

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

09:42 (24 HR)

Collection date and time (derived)

11 JAN 2021 09:42

US3442173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	09:39
Collection Date and Time (derived)	11 JAN 2021 09:39

US3442173

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 09:25
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 10:16
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3442173

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 19:12:45

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3442173

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

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) 5 FEB 2021

What was the treatment time? (00:00-23:59) 09:44 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 09:44

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

US3442173

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:12:44

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442173

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 19:13:00

Generated On: 11 Aug 2021 22:43:12

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442173

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:46 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 14:46
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3442173

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3442173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

14:55 (24 HR)

Collection date and time (derived)

2 MAR 2021 14:55

US3442173

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

AEID

Adverse event

BROKEN TOES: RIGHT 3RD AND
4TH

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)

28 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

AEID	USA-US017-2021-MRNA-1273-P30 1000007
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	04 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 DEC 2020
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"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Mar 2021 21:46:31

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication OZEMPIC

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication BELSOMRA

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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 OCT 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication ARIPRIPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication TRINTELLIX

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 (4)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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 2016	
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) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (5)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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 2019	
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) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication TRELEGY

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 100/62.5/25

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) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BROKEN TOES: RIGHT 3RD AND 4TH
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication FLUZONE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration 0.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

	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)		5 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 NOV 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 (9)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:28:16

Generated On: 11 Aug 2021 22:43:12

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

US3442173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 19:12:43

Generated On: 11 Aug 2021 22:43:12

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

Generated On: 11 Aug 2021 22:43:12

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:43:12

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 ☐

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

SAEID	USA-US017-2021-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

SAEID	USA-US017-2021-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/JAN/2021 23:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 15:28:17

Generated On: 11 Aug 2021 22:43:12

SAEID	USA-US017-2021-MRNA-1273-P301000007
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/MAR/2021 15:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3442173 (Prod: Benchmark Research - Fort Worth)

US3442173

Form: Participant Creation

Generated On: 11 Aug 2021 22:43:12

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'US3442173'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 15:50:08

US3442173

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:29

US3442173

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 15:50:09

US3442173

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[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 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:29

US3442173

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'SCRN'	System	16 Sep 2020 16:47:29

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 15:50:10

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered '52'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'YEARS'	System	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '52'	System	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Female (F)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'I'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered '0'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered '0'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered '0'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered empty.	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered '0'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:47:51

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Sep 2020'	System	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2020'	System	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Amendment 3 (3)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered empty.	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered empty.	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:01

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 15:50:09

US3442173

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'I'	System	16 Sep 2020 16:48:06

US3442173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:06

US3442173

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:43:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:34:23

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:25:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:25:41
Data point term sent to Coder	System	16 Sep 2020 18:35:45
User entered 'penicillin allergy: hives rash'	(b) (4), (b) (6)	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 1980'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 1980'	System	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '1980'	System	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:35:12

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:36:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:36:45
Data point term sent to Coder	System	16 Sep 2020 18:35:46
User entered 'gerd'	(b) (4), (b) (6)	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2000'	System	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2000'	System	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:35:24

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:37:47
Data point term sent to Coder	System	16 Sep 2020 18:36:46
User entered 'heartburn'	(b) (4), (b) (6)	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2000'	System	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2000'	System	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:35:49

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:37:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:37:46
Data point term sent to Coder	System	16 Sep 2020 18:36:49
User entered 'cholelithiasis'	(b) (4), (b) (6)	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2008'	System	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2008'	System	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2008'	System	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2008'	System	16 Sep 2020 18:36:33

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:38:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:38:50
Data point term sent to Coder	System	16 Sep 2020 18:37:49
User entered 'irritable bowel syndrome'	(b) (4), (b) (6)	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2019'	System	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2019'	System	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:37:02

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:38:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:38:48
Data point term sent to Coder	System	16 Sep 2020 18:37:49
User entered 'cataracts'	(b) (4), (b) (6)	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2014'	System	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2014'	System	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2014'	System	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2014'	System	16 Sep 2020 18:37:24

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:43:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 18:43:47
Data point term sent to Coder	System	16 Sep 2020 18:42:55
User entered 'tonsillitis'	(b) (4), (b) (6)	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 1995'	System	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '1995'	System	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 18:42:10

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 19:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:54:41
Data point term sent to Coder	System	16 Sep 2020 19:53:36
User entered 'diabetes type 2'	(b) (4), (b) (6)	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2018'	System	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2018'	System	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:52:38

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
Data point term sent to Coder	System	16 Sep 2020 19:53:40
User entered 'hot flashes'	(b) (4), (b) (6)	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2017'	System	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2017'	System	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:52:51

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
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)	16 Sep 2020 19:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
Data point term sent to Coder	System	16 Sep 2020 19:53:36
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 1994'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 1994'	System	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '1994'	System	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:53:10

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
Data point term sent to Coder	System	16 Sep 2020 19:53:40
User entered 'copd'	(b) (4), (b) (6)	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2014'	System	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2014'	System	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:53:28

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:54:41
Data point term sent to Coder	System	16 Sep 2020 19:53:42
User entered 'depression'	(b) (4), (b) (6)	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2000'	System	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2000'	System	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:53:42

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:55:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:55:43
Data point term sent to Coder	System	16 Sep 2020 19:54:43
User entered 'anxiety'	(b) (4), (b) (6)	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2000'	System	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2000'	System	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:54:00

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:57:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:57:46
Data point term sent to Coder	System	16 Sep 2020 19:56:46
User entered 'insomnia'	(b) (4), (b) (6)	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2019'	System	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2019'	System	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:56:28

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:58:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:58:48
Data point term sent to Coder	System	16 Sep 2020 19:57:49
User entered 'lumbar back pain'	(b) (4), (b) (6)	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2018'	System	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2018'	System	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered empty.	System	16 Sep 2020 19:56:49

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:58:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:58:48
Data point term sent to Coder	System	16 Sep 2020 19:57:49
User entered 'hysterectomy'	(b) (4), (b) (6)	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2017'	System	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2017'	System	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2017'	System	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2017'	System	16 Sep 2020 19:57:13

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 19:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 19:10:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:58:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:58:49
Data point term sent to Coder	System	16 Sep 2020 19:57:51
User entered 'gall bladder removal'	(b) (4), (b) (6)	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2008'	System	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2008'	System	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2008'	System	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2008'	System	16 Sep 2020 19:57:33

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:59:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 19:59:38
Data point term sent to Coder	System	16 Sep 2020 19:58:54
User entered 'cataract removal'	(b) (4), (b) (6)	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2014'	System	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2014'	System	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2014'	System	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2014'	System	16 Sep 2020 19:57:55

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 18:41:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 18:41:55
Data point term sent to Coder	System	15 Oct 2020 18:41:04
User entered 'menorrhagia'	(b) (4), (b) (6)	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2017'	System	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2017'	System	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'Jan 2017'	System	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '2017'	System	15 Oct 2020 18:40:21

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:00'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '16 Sep 2020 11:00'	System	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '65' in	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00
DataPoint set to visible.	System	16 Sep 2020 16:48:06

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '201' lb	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00
DataPoint set to visible.	System	16 Sep 2020 16:48:06

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered '33.51809'	System	16 Sep 2020 18:28:00
DataPoint set to visible.	System	16 Sep 2020 16:48:06

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'kg/m2'	System	16 Sep 2020 18:28:00
DataPoint set to visible.	System	16 Sep 2020 16:48:06

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'bpm'	System	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'breaths/min'	System	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'mmHg'	System	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User entered 'mmHg'	System	16 Sep 2020 18:28:00

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10

US3442173

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10

US3442173

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:34:17

US3442173

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:34:17

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:20:48
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:40:33
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:06:52
User closed query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		17 Sep 2020 00:37:04
User opened query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		16 Sep 2020 18:34:01
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	16 Sep 2020 18:34:01
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:34:01
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	16 Sep 2020 18:33:54

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User closed query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	16 Sep 2020 18:33:54
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:33:54
User opened query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	16 Sep 2020 18:33:19
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty; reason for change Per Query Resolution	(b) (4)	17 Sep 2020 00:37:04
User entered 'bilateral tubal ligation and complete hysterectomy'	(b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:43:12

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:33:19

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'disability'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

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)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:00:10
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:26:43

US3442173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	16 Sep 2020 16:48:38

US3442173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	16 Sep 2020 16:48:38

US3442173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Clinic (Clinic)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 16:48:38

US3442173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'VISIT1'	System	16 Sep 2020 16:48:38

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 16:44:35

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '146431'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 16:44:35

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 16:44:35

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:27:04

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:27:04

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:27:04

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:27:04

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:27:04

US3442173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:12

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:46:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:20:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:20:41

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Pre-Dose (PREDOSE)'		16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:00'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '16 Sep 2020 11:00'	System	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '60'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'bpm'	System	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'breaths/min'	System	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '132'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '80'	(b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:36

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Post-Dose (POSTDOSE)'		16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12:33'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '16 Sep 2020 12:33'	System	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '97.7' F	(b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '62'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'bpm'	System	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'breaths/min'	System	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '154'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	16 Sep 2020 19:59:37

US3442173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:31:44

US3442173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:31:44

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:13:01
User entered empty.	Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12:07'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '16 Sep 2020 12:07'	System	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'ONCE'	System	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 17:09:10

US3442173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:21

US3442173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:21

US3442173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:20'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:21

US3442173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '16 Sep 2020 11:20'	System	16 Sep 2020 19:58:21

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:28'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '16 Sep 2020 11:28'	System	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	16 Sep 2020 19:58:34

US3442173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:32

US3442173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '1'	System	16 Sep 2020 18:24:32

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:40:25', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '67a37c76-0fb5-4b8f-8f92-21178703823f' User entered 'Yes (Y)'	System	16 Sep 2020 17:41:10
	System	16 Sep 2020 17:41:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:40:35', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '67a37c76-0fb5-4b8f-8f92-21178703823f' User entered '97.7'	System	16 Sep 2020 17:41:10
	System	16 Sep 2020 17:41:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:40:40', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '67a37c76-0fb5-4b8f-8f92-21178703823f' User entered 'No (N)'	System	16 Sep 2020 17:41:10
	System	16 Sep 2020 17:41:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:40:47', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '67a37c76-0fb5-4b8f-8f92-21178703823f' User entered '16 Sep 2020 12:40'	System	16 Sep 2020 17:41:10
	System	16 Sep 2020 17:41:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 12:27'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 14:57'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:24:32', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bfa44c14-633c-46ac-95a7-970f75a3c8af' User entered 'Yes (Y)'	System	16 Sep 2020 22:24:56
	System	16 Sep 2020 22:24:56

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:24:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bfa44c14-633c-46ac-95a7-970f75a3c8af' User entered '97.6'	System	16 Sep 2020 22:24:56
	System	16 Sep 2020 22:24:56

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:24:49', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bfa44c14-633c-46ac-95a7-970f75a3c8af' User entered 'No (N)'	System	16 Sep 2020 22:24:56
	System	16 Sep 2020 22:24:56

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:24:55', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bfa44c14-633c-46ac-95a7-970f75a3c8af' User entered '16 Sep 2020 17:24'	System	16 Sep 2020 22:24:56
	System	16 Sep 2020 22:24:56

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 15:52'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 2'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:09:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '524b78f3-8084-41c7-8769-b39ee3f8802f' User entered 'Yes (Y)'	System	17 Sep 2020 23:09:54
	System	17 Sep 2020 23:09:54

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:09:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '524b78f3-8084-41c7-8769-b39ee3f8802f' User entered '98.4'	System	17 Sep 2020 23:09:54
	System	17 Sep 2020 23:09:54

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:09:46', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '524b78f3-8084-41c7-8769-b39ee3f8802f' User entered 'No (N)'	System	17 Sep 2020 23:09:54
	System	17 Sep 2020 23:09:54

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:09:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '524b78f3-8084-41c7-8769-b39ee3f8802f' User entered '17 Sep 2020 18:09'	System	17 Sep 2020 23:09:54
	System	17 Sep 2020 23:09:54

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 3'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:10', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'a4ce456f-f635-4e00-9917-c3ca311bd804' User entered 'Yes (Y)'	System	18 Sep 2020 17:07:28
	System	18 Sep 2020 17:07:28

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:17', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'a4ce456f-f635-4e00-9917-c3ca311bd804' User entered '97.6'	System	18 Sep 2020 17:07:28
	System	18 Sep 2020 17:07:28

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:21', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'a4ce456f-f635-4e00-9917-c3ca311bd804'	System	18 Sep 2020 17:07:28
User entered 'No (N)'	System	18 Sep 2020 17:07:28

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'a4ce456f-f635-4e00-9917-c3ca311bd804' User entered '18 Sep 2020 12:07'	System	18 Sep 2020 17:07:28
	System	18 Sep 2020 17:07:28

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 4'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:41:53', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '75f52ca7-f095-4de4-9513-950995c08bbb' User entered 'No (N)'	System	20 Sep 2020 01:42:14
	System	20 Sep 2020 01:42:14

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '75f52ca7-f095-4de4-9513-950995c08bbb' User entered 'No (N)'	System	20 Sep 2020 01:42:14
	System	20 Sep 2020 01:42:14

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:09', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '75f52ca7-f095-4de4-9513-950995c08bbb' User entered '19 Sep 2020 20:42'	System	20 Sep 2020 01:42:14
	System	20 Sep 2020 01:42:14

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 5'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:06:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '739be6d3-b9a9-4b4e-a41b-c30c5424ec48'	System	20 Sep 2020 17:08:30
User entered 'Yes (Y)'	System	20 Sep 2020 17:08:30

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:08:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '739be6d3-b9a9-4b4e-a41b-c30c5424ec48' User entered '97.6'	System	20 Sep 2020 17:08:30
	System	20 Sep 2020 17:08:30

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:08:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '739be6d3-b9a9-4b4e-a41b-c30c5424ec48'	System	20 Sep 2020 17:08:30
User entered 'No (N)'	System	20 Sep 2020 17:08:30

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:08:29', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '739be6d3-b9a9-4b4e-a41b-c30c5424ec48'	System	20 Sep 2020 17:08:30
User entered '20 Sep 2020 12:08'	System	20 Sep 2020 17:08:30

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 6'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:22', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f3e81de8-6957-4d7f-ae84-e8542b48631a' User entered 'Yes (Y)'	System	22 Sep 2020 14:17:57
	System	22 Sep 2020 14:17:57

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:28', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f3e81de8-6957-4d7f-ae84-e8542b48631a' User entered '97.6'	System	22 Sep 2020 14:17:57
	System	22 Sep 2020 14:17:57

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:31', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f3e81de8-6957-4d7f-ae84-e8542b48631a' User entered 'No (N)'	System	22 Sep 2020 14:17:57
	System	22 Sep 2020 14:17:57

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:35', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f3e81de8-6957-4d7f-ae84-e8542b48631a' User entered '22 Sep 2020 09:17'	System	22 Sep 2020 14:17:57
	System	22 Sep 2020 14:17:57

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 7'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:03:58', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '730ca7ae-4bb4-4717-8abf-03f4cc011e6a' User entered 'Yes (Y)'	System	22 Sep 2020 17:07:10
	System	22 Sep 2020 17:07:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:02', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '730ca7ae-4bb4-4717-8abf-03f4cc011e6a' User entered '97.2'	System	22 Sep 2020 17:07:10
	System	22 Sep 2020 17:07:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:05', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '730ca7ae-4bb4-4717-8abf-03f4cc011e6a'	System	22 Sep 2020 17:07:10
User entered 'No (N)'	System	22 Sep 2020 17:07:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:08', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '730ca7ae-4bb4-4717-8abf-03f4cc011e6a'	System	22 Sep 2020 17:07:10
User entered '22 Sep 2020 12:04'	System	22 Sep 2020 17:07:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e2612b24-8198-4c32-86e6-adf6f4b8a968'	System	16 Sep 2020 17:41:31
User entered 'None (1)'	System	16 Sep 2020 17:41:31

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:06', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e2612b24-8198-4c32-86e6-adf6f4b8a968' User entered 'No (N)'	System	16 Sep 2020 17:41:31
	System	16 Sep 2020 17:41:31

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:17', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e2612b24-8198-4c32-86e6-adf6f4b8a968' User entered 'No (N)'	System	16 Sep 2020 17:41:31
	System	16 Sep 2020 17:41:31

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:23', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e2612b24-8198-4c32-86e6-adf6f4b8a968'	System	16 Sep 2020 17:41:31
User entered 'None (1)'	System	16 Sep 2020 17:41:31

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:26', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e2612b24-8198-4c32-86e6-adf6f4b8a968' User entered '16 Sep 2020 12:41'	System	16 Sep 2020 17:41:31
	System	16 Sep 2020 17:41:31

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 12:27'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 14:57'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:18', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '28e4c759-37c5-40fb-ad7f-2a295e401eca'	System	16 Sep 2020 22:25:38
User entered 'None (1)'	System	16 Sep 2020 22:25:38

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:22', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '28e4c759-37c5-40fb-ad7f-2a295e401eca' User entered 'No (N)'	System	16 Sep 2020 22:25:38
	System	16 Sep 2020 22:25:38

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:25', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '28e4c759-37c5-40fb-ad7f-2a295e401eca' User entered 'No (N)'	System	16 Sep 2020 22:25:38
	System	16 Sep 2020 22:25:38

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:29', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '28e4c759-37c5-40fb-ad7f-2a295e401eca' User entered 'None (1)'	System	16 Sep 2020 22:25:38
	System	16 Sep 2020 22:25:38

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:32', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '28e4c759-37c5-40fb-ad7f-2a295e401eca' User entered '16 Sep 2020 17:25'	System	16 Sep 2020 22:25:38
	System	16 Sep 2020 22:25:38

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 15:52'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 2'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:09:58', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6ac0af54-8cb9-48d9-a621-cc9ed8438f44'	System	17 Sep 2020 23:10:42
User entered 'None (1)'	System	17 Sep 2020 23:10:42

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6ac0af54-8cb9-48d9-a621-cc9ed8438f44'	System	17 Sep 2020 23:10:42
User entered 'No (N)'	System	17 Sep 2020 23:10:42

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6ac0af54-8cb9-48d9-a621-cc9ed8438f44'	System	17 Sep 2020 23:10:42
User entered 'No (N)'	System	17 Sep 2020 23:10:42

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6ac0af54-8cb9-48d9-a621-cc9ed8438f44'	System	17 Sep 2020 23:10:42
User entered 'None (1)'	System	17 Sep 2020 23:10:42

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6ac0af54-8cb9-48d9-a621-cc9ed8438f44'	System	17 Sep 2020 23:10:42
User entered '17 Sep 2020 18:10'	System	17 Sep 2020 23:10:42

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 3'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '70b1a672-1771-49c2-b40d-df4070eaad76'	System	18 Sep 2020 17:07:50
User entered 'None (1)'	System	18 Sep 2020 17:07:50

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '70b1a672-1771-49c2-b40d-df4070eaad76' User entered 'No (N)'	System	18 Sep 2020 17:07:50
	System	18 Sep 2020 17:07:50

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '70b1a672-1771-49c2-b40d-df4070eaad76' User entered 'No (N)'	System	18 Sep 2020 17:07:50
	System	18 Sep 2020 17:07:50

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '70b1a672-1771-49c2-b40d-df4070eaad76' User entered 'None (1)'	System	18 Sep 2020 17:07:50
	System	18 Sep 2020 17:07:50

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:48', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '70b1a672-1771-49c2-b40d-df4070eaad76' User entered '18 Sep 2020 12:07'	System	18 Sep 2020 17:07:50
	System	18 Sep 2020 17:07:50

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 4'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:17', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c9e6df52-0cf9-440a-b1c8-863a74eeb6bb'	System	20 Sep 2020 01:42:39
User entered 'None (1)'	System	20 Sep 2020 01:42:39

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c9e6df52-0cf9-440a-b1c8-863a74eeb6bb' User entered 'No (N)'	System	20 Sep 2020 01:42:39
	System	20 Sep 2020 01:42:39

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c9e6df52-0cf9-440a-b1c8-863a74eeb6bb'	System	20 Sep 2020 01:42:39
User entered 'No (N)'	System	20 Sep 2020 01:42:39

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:31', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c9e6df52-0cf9-440a-b1c8-863a74eeb6bb'	System	20 Sep 2020 01:42:39
User entered 'None (1)'	System	20 Sep 2020 01:42:39

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:36', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c9e6df52-0cf9-440a-b1c8-863a74eeb6bb' User entered '19 Sep 2020 20:42'	System	20 Sep 2020 01:42:39
	System	20 Sep 2020 01:42:39

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 5'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:08:58', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0ac38ab1-8580-4b69-b431-f89ae2dc2cb1' User entered 'None (1)'	System	20 Sep 2020 17:09:09
	System	20 Sep 2020 17:09:09

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0ac38ab1-8580-4b69-b431-f89ae2dc2cb1' User entered 'No (N)'	System	20 Sep 2020 17:09:09
	System	20 Sep 2020 17:09:09

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:02', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0ac38ab1-8580-4b69-b431-f89ae2dc2cb1' User entered 'No (N)'	System	20 Sep 2020 17:09:09
	System	20 Sep 2020 17:09:09

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:05', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0ac38ab1-8580-4b69-b431-f89ae2dc2cb1' User entered 'None (1)'	System	20 Sep 2020 17:09:09
	System	20 Sep 2020 17:09:09

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0ac38ab1-8580-4b69-b431-f89ae2dc2cb1' User entered '20 Sep 2020 12:09'	System	20 Sep 2020 17:09:09
	System	20 Sep 2020 17:09:09

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 6'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '98764eda-4eb3-4053-bbd9-2241a241d9d7'	System	22 Sep 2020 14:18:00
User entered 'None (1)'	System	22 Sep 2020 14:18:00

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:42', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '98764eda-4eb3-4053-bbd9-2241a241d9d7'	System	22 Sep 2020 14:18:00
User entered 'No (N)'	System	22 Sep 2020 14:18:00

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '98764eda-4eb3-4053-bbd9-2241a241d9d7'	System	22 Sep 2020 14:18:00
User entered 'No (N)'	System	22 Sep 2020 14:18:00

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:48', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '98764eda-4eb3-4053-bbd9-2241a241d9d7'	System	22 Sep 2020 14:18:00
User entered 'None (1)'	System	22 Sep 2020 14:18:00

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:50', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '98764eda-4eb3-4053-bbd9-2241a241d9d7'	System	22 Sep 2020 14:18:00
User entered '22 Sep 2020 09:17'	System	22 Sep 2020 14:18:00

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 7'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'de0c91a1-461b-4983-bd07-3f41dee20883'	System	22 Sep 2020 17:07:21
User entered 'None (1)'	System	22 Sep 2020 17:07:21

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'de0c91a1-461b-4983-bd07-3f41dee20883'	System	22 Sep 2020 17:07:21
User entered 'No (N)'	System	22 Sep 2020 17:07:21

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'de0c91a1-461b-4983-bd07-3f41dee20883'	System	22 Sep 2020 17:07:21
User entered 'No (N)'	System	22 Sep 2020 17:07:21

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'de0c91a1-461b-4983-bd07-3f41dee20883'	System	22 Sep 2020 17:07:21
User entered 'None (1)'	System	22 Sep 2020 17:07:21

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:26', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'de0c91a1-461b-4983-bd07-3f41dee20883' User entered '22 Sep 2020 12:04'	System	22 Sep 2020 17:07:21
	System	22 Sep 2020 17:07:21

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:34', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'None (0)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'None (0)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:40', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'None (0)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:42', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'None (0)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'None (0)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:48', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'None (0)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:52', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered 'No (N)'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T12:41:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5969fb97-1e42-42b2-b3a9-e88336fc45c1' User entered '16 Sep 2020 12:41'	System	16 Sep 2020 17:41:59
	System	16 Sep 2020 17:41:59

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 12:27'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 14:57'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:40', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered 'None (0)'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:43', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered 'None (0)'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:46', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered 'None (0)'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:49', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered 'None (0)'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered 'None (0)'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:25:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered 'None (0)'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:26:02', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0'	System	16 Sep 2020 22:26:07
User entered 'No (N)'	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-16T17:26:04', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '88b3bb35-50ea-45e3-adf5-84b3a6a840b0' User entered '16 Sep 2020 17:26'	System	16 Sep 2020 22:26:07
	System	16 Sep 2020 22:26:07

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Sep 2020 15:52'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 2'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:48', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'None (0)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:53', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'None (0)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:10:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'None (0)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:11:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'None (0)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:11:02', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'None (0)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:11:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'None (0)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:11:15', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered 'No (N)'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-17T18:11:17', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'db403a7d-cc46-47d2-9d7b-d3f1c796dc41' User entered '17 Sep 2020 18:11'	System	17 Sep 2020 23:11:20
	System	17 Sep 2020 23:11:20

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 3'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:52', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'None (0)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:55', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'None (0)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:07:59', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'None (0)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:08:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'None (0)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:08:04', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'None (0)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:08:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'None (0)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:08:11', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered 'No (N)'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-18T12:08:14', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3ddaf81e-016a-4a91-8a7b-db3137a2648f' User entered '18 Sep 2020 12:08'	System	18 Sep 2020 17:08:19
	System	18 Sep 2020 17:08:19

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 4'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:46', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584' User entered 'None (0)'	System	20 Sep 2020 01:43:16
	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584' User entered 'None (0)'	System	20 Sep 2020 01:43:16
	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584' User entered 'None (0)'	System	20 Sep 2020 01:43:16
	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584' User entered 'None (0)'	System	20 Sep 2020 01:43:16
	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:42:59', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584' User entered 'None (0)'	System	20 Sep 2020 01:43:16
	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:43:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584'	System	20 Sep 2020 01:43:16
User entered 'None (0)'	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:43:09', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584'	System	20 Sep 2020 01:43:16
User entered 'No (N)'	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-19T20:43:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'f2db5356-c146-4a81-9e44-99fe04243584' User entered '19 Sep 2020 20:43'	System	20 Sep 2020 01:43:16
	System	20 Sep 2020 01:43:16

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 5'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:11', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'None (0)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:12', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'None (0)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:14', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'None (0)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'None (0)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:18', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'None (0)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'None (0)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:25', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered 'No (N)'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-20T12:09:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bc299771-66d7-4675-8c79-b293154b45dc' User entered '20 Sep 2020 12:09'	System	20 Sep 2020 17:09:29
	System	20 Sep 2020 17:09:29

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 6'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:55', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'None (0)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:17:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'None (0)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:18:04', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'None (0)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:18:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'None (0)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:18:10', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'None (0)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:18:12', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'None (0)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:18:17', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered 'No (N)'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T09:18:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '611afda0-9a67-42de-b185-a64d3bc1cfbc' User entered '22 Sep 2020 09:18'	System	22 Sep 2020 14:18:23
	System	22 Sep 2020 14:18:23

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 7'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:31', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4'	System	22 Sep 2020 17:07:43
User entered 'None (0)'	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4' User entered 'None (0)'	System	22 Sep 2020 17:07:43
	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:35', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4' User entered 'None (0)'	System	22 Sep 2020 17:07:43
	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4' User entered 'None (0)'	System	22 Sep 2020 17:07:43
	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4' User entered 'None (0)'	System	22 Sep 2020 17:07:43
	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:43', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4' User entered 'None (0)'	System	22 Sep 2020 17:07:43
	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:50', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4'	System	22 Sep 2020 17:07:43
User entered 'No (N)'	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-09-22T12:04:53', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '80204ce0-94ef-482b-ba13-83d695e1e2a4' User entered '22 Sep 2020 12:04'	System	22 Sep 2020 17:07:43
	System	22 Sep 2020 17:07:43

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:09:10

US3442173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:46:53

US3442173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:46:53

US3442173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:46:53

US3442173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:46:53

US3442173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 15:46:58

US3442173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	25 Sep 2020 15:46:58

US3442173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:54:10

US3442173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:54:10

US3442173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:54:10

US3442173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:54:10

US3442173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 21:54:15

US3442173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	30 Sep 2020 21:54:15

US3442173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:50:55

US3442173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:50:55

US3442173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:50:55

US3442173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:50:55

US3442173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 21:51:00

US3442173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	07 Oct 2020 21:51:00

US3442173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:52:49

US3442173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:52:49

US3442173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:52:49

US3442173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'VISIT2'	System	15 Oct 2020 16:52:49

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Pre-Dose (PREDOSE)'		15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:14'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '15 Oct 2020 11:14'	System	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '59'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'bpm'	System	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'breaths/min'	System	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '145'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '82'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	15 Oct 2020 17:35:08

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Post-Dose (POSTDOSE)'		15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12:20'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '15 Oct 2020 12:20'	System	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '97.6' F	(b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '62'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'bpm'	System	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'breaths/min'	System	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '145'	(b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '90'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'mmHg'	System	15 Oct 2020 17:36:45

US3442173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:27

US3442173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:27

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:48'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '15 Oct 2020 11:48'	System	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'ONCE'	System	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 16:53:13

US3442173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:44

US3442173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:44

US3442173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:18'	(b) (4), (b) (6)	15 Oct 2020 17:35:44

US3442173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '15 Oct 2020 11:18'	System	15 Oct 2020 17:35:44

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '11:20'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '15 Oct 2020 11:20'	System	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	15 Oct 2020 17:35:57

US3442173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:53:21

US3442173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '1'	System	15 Oct 2020 16:53:21

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:20:03', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e1dc80c3-9a73-4b54-96f1-773c9e0acffc' User entered 'Yes (Y)'	System	15 Oct 2020 17:21:59
	System	15 Oct 2020 17:21:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:21:48', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e1dc80c3-9a73-4b54-96f1-773c9e0acffc' User entered '97.6'	System	15 Oct 2020 17:21:59
	System	15 Oct 2020 17:21:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:21:52', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e1dc80c3-9a73-4b54-96f1-773c9e0acffc'	System	15 Oct 2020 17:21:59
User entered 'No (N)'	System	15 Oct 2020 17:21:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:21:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e1dc80c3-9a73-4b54-96f1-773c9e0acffc' User entered '15 Oct 2020 12:21'	System	15 Oct 2020 17:21:59
	System	15 Oct 2020 17:21:59

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 12:08'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 14:38'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:52:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6cd1e62d-ceba-4409-83ea-39650bd665a1' User entered 'Yes (Y)'	System	16 Oct 2020 00:53:09
	System	16 Oct 2020 00:53:09

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:52:49', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6cd1e62d-ceba-4409-83ea-39650bd665a1' User entered '97.9'	System	16 Oct 2020 00:53:09
	System	16 Oct 2020 00:53:09

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:52:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6cd1e62d-ceba-4409-83ea-39650bd665a1' User entered 'No (N)'	System	16 Oct 2020 00:53:09
	System	16 Oct 2020 00:53:09

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:05', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6cd1e62d-ceba-4409-83ea-39650bd665a1' User entered '15 Oct 2020 19:53'	System	16 Oct 2020 00:53:09
	System	16 Oct 2020 00:53:09

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 15:33'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 2'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bd02858b-cbb4-4754-8139-a3355aabb745'	System	16 Oct 2020 23:01:18
User entered 'Yes (Y)'	System	16 Oct 2020 23:01:18

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:01:06', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bd02858b-cbb4-4754-8139-a3355aabb745'	System	16 Oct 2020 23:01:18
User entered '96.8'	System	16 Oct 2020 23:01:18

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:01:12', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bd02858b-cbb4-4754-8139-a3355aabb745'	System	16 Oct 2020 23:01:18
User entered 'No (N)'	System	16 Oct 2020 23:01:18

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:01:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'bd02858b-cbb4-4754-8139-a3355aabb745'	System	16 Oct 2020 23:01:18
User entered '16 Oct 2020 18:01'	System	16 Oct 2020 23:01:18

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 3'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9a1b5366-9515-4de3-861f-48e261b2785a' User entered 'Yes (Y)'	System	17 Oct 2020 18:52:41
	System	17 Oct 2020 18:52:41

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:32', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9a1b5366-9515-4de3-861f-48e261b2785a' User entered '97.5'	System	17 Oct 2020 18:52:41
	System	17 Oct 2020 18:52:41

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:35', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9a1b5366-9515-4de3-861f-48e261b2785a' User entered 'No (N)'	System	17 Oct 2020 18:52:41
	System	17 Oct 2020 18:52:41

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9a1b5366-9515-4de3-861f-48e261b2785a' User entered '17 Oct 2020 13:52'	System	17 Oct 2020 18:52:41
	System	17 Oct 2020 18:52:41

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 4'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:06', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'ec3ce2c5-1eb5-44f5-8bcc-98367738585f' User entered 'Yes (Y)'	System	18 Oct 2020 21:42:32
	System	18 Oct 2020 21:42:32

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:14', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'ec3ce2c5-1eb5-44f5-8bcc-98367738585f' User entered '97.2'	System	18 Oct 2020 21:42:32
	System	18 Oct 2020 21:42:32

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:18', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'ec3ce2c5-1eb5-44f5-8bcc-98367738585f' User entered 'No (N)'	System	18 Oct 2020 21:42:32
	System	18 Oct 2020 21:42:32

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:29', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'ec3ce2c5-1eb5-44f5-8bcc-98367738585f' User entered '18 Oct 2020 16:42'	System	18 Oct 2020 21:42:32
	System	18 Oct 2020 21:42:32

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 5'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'b36ab35f-bf58-49a6-a880-0bca2013891c' User entered 'Yes (Y)'	System	19 Oct 2020 17:14:31
	System	19 Oct 2020 17:14:31

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:21', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'b36ab35f-bf58-49a6-a880-0bca2013891c' User entered '97.5'	System	19 Oct 2020 17:14:31
	System	19 Oct 2020 17:14:31

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'b36ab35f-bf58-49a6-a880-0bca2013891c' User entered 'No (N)'	System	19 Oct 2020 17:14:31
	System	19 Oct 2020 17:14:31

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:28', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'b36ab35f-bf58-49a6-a880-0bca2013891c' User entered '19 Oct 2020 12:14'	System	19 Oct 2020 17:14:31
	System	19 Oct 2020 17:14:31

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 6'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:17', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c4b2173f-7717-45b6-9623-2bf3b2ed885a' User entered 'Yes (Y)'	System	20 Oct 2020 23:10:37
	System	20 Oct 2020 23:10:37

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:23', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c4b2173f-7717-45b6-9623-2bf3b2ed885a' User entered '97.2'	System	20 Oct 2020 23:10:37
	System	20 Oct 2020 23:10:37

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:29', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c4b2173f-7717-45b6-9623-2bf3b2ed885a' User entered 'No (N)'	System	20 Oct 2020 23:10:37
	System	20 Oct 2020 23:10:37

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c4b2173f-7717-45b6-9623-2bf3b2ed885a' User entered '20 Oct 2020 18:10'	System	20 Oct 2020 23:10:37
	System	20 Oct 2020 23:10:37

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 7'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '8d2a9759-bb8a-469e-9f2d-5b8686a34d3b' User entered 'Yes (Y)'	System	21 Oct 2020 20:01:49
	System	21 Oct 2020 20:01:49

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:42', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '8d2a9759-bb8a-469e-9f2d-5b8686a34d3b' User entered '97.8'	System	21 Oct 2020 20:01:49
	System	21 Oct 2020 20:01:49

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '8d2a9759-bb8a-469e-9f2d-5b8686a34d3b' User entered 'No (N)'	System	21 Oct 2020 20:01:49
	System	21 Oct 2020 20:01:49

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:47', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '8d2a9759-bb8a-469e-9f2d-5b8686a34d3b' User entered '21 Oct 2020 15:01'	System	21 Oct 2020 20:01:49
	System	21 Oct 2020 20:01:49

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:19:15', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '4e4b33d2-71cd-42c4-a50b-d6f48e98be46'	System	15 Oct 2020 17:19:42
User entered 'None (1)'	System	15 Oct 2020 17:19:42

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:19:21', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '4e4b33d2-71cd-42c4-a50b-d6f48e98be46' User entered 'No (N)'	System	15 Oct 2020 17:19:42
	System	15 Oct 2020 17:19:42

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:19:28', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '4e4b33d2-71cd-42c4-a50b-d6f48e98be46' User entered 'No (N)'	System	15 Oct 2020 17:19:42
	System	15 Oct 2020 17:19:42

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:19:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '4e4b33d2-71cd-42c4-a50b-d6f48e98be46'	System	15 Oct 2020 17:19:42
User entered 'None (1)'	System	15 Oct 2020 17:19:42

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:19:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '4e4b33d2-71cd-42c4-a50b-d6f48e98be46' User entered '15 Oct 2020 12:19'	System	15 Oct 2020 17:19:42
	System	15 Oct 2020 17:19:42

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 12:08'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 14:38'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:15', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '46ca41de-8bff-4dc7-9061-27276ea3badb'	System	16 Oct 2020 00:53:50
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 00:53:50

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:21', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '46ca41de-8bff-4dc7-9061-27276ea3badb' User entered 'No (N)'	System	16 Oct 2020 00:53:50
	System	16 Oct 2020 00:53:50

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '46ca41de-8bff-4dc7-9061-27276ea3badb' User entered 'No (N)'	System	16 Oct 2020 00:53:50
	System	16 Oct 2020 00:53:50

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:43', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '46ca41de-8bff-4dc7-9061-27276ea3badb' User entered 'None (1)'	System	16 Oct 2020 00:53:50
	System	16 Oct 2020 00:53:50

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:46', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '46ca41de-8bff-4dc7-9061-27276ea3badb' User entered '15 Oct 2020 19:53'	System	16 Oct 2020 00:53:50
	System	16 Oct 2020 00:53:50

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 15:33'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 2'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'da623051-0d01-49ee-848c-fdec6c6c5f1'	System	16 Oct 2020 23:00:49
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 23:00:49

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'da623051-0d01-49ee-848c-fdec6c6c5f1'	System	16 Oct 2020 23:00:49
User entered 'No (N)'	System	16 Oct 2020 23:00:49

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'da623051-0d01-49ee-848c-fdec6c6c5f1'	System	16 Oct 2020 23:00:49
User entered 'No (N)'	System	16 Oct 2020 23:00:49

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:44', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'da623051-0d01-49ee-848c-fdecb6c6c5f1'	System	16 Oct 2020 23:00:49
User entered 'None (1)'	System	16 Oct 2020 23:00:49

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:47', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'da623051-0d01-49ee-848c-fdec6c6c5f1'	System	16 Oct 2020 23:00:49
User entered '16 Oct 2020 18:00'	System	16 Oct 2020 23:00:49

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 3'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3eefa22c-fe2c-43dc-962d-4b80ef7a67c5'	System	17 Oct 2020 18:53:05
User entered 'None (1)'	System	17 Oct 2020 18:53:05

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3eefa22c-fe2c-43dc-962d-4b80ef7a67c5' User entered 'No (N)'	System	17 Oct 2020 18:53:05
	System	17 Oct 2020 18:53:05

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:52:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3eefa22c-fe2c-43dc-962d-4b80ef7a67c5'	System	17 Oct 2020 18:53:05
User entered 'No (N)'	System	17 Oct 2020 18:53:05

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3eefa22c-fe2c-43dc-962d-4b80ef7a67c5'	System	17 Oct 2020 18:53:05
User entered 'None (1)'	System	17 Oct 2020 18:53:05

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:02', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '3eefa22c-fe2c-43dc-962d-4b80ef7a67c5' User entered '17 Oct 2020 13:53'	System	17 Oct 2020 18:53:05
	System	17 Oct 2020 18:53:05

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 4'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd52b1911-d060-4a69-b798-475712ae8f93'	System	18 Oct 2020 21:42:48
User entered 'None (1)'	System	18 Oct 2020 21:42:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd52b1911-d060-4a69-b798-475712ae8f93' User entered 'No (N)'	System	18 Oct 2020 21:42:48
	System	18 Oct 2020 21:42:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:40', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd52b1911-d060-4a69-b798-475712ae8f93' User entered 'No (N)'	System	18 Oct 2020 21:42:48
	System	18 Oct 2020 21:42:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:42', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd52b1911-d060-4a69-b798-475712ae8f93'	System	18 Oct 2020 21:42:48
User entered 'None (1)'	System	18 Oct 2020 21:42:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd52b1911-d060-4a69-b798-475712ae8f93' User entered '18 Oct 2020 16:42'	System	18 Oct 2020 21:42:48
	System	18 Oct 2020 21:42:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 5'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fa30aad3-8b0b-4881-8730-748f50922a0e'	System	19 Oct 2020 17:14:48
User entered 'None (1)'	System	19 Oct 2020 17:14:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:36', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fa30aad3-8b0b-4881-8730-748f50922a0e' User entered 'No (N)'	System	19 Oct 2020 17:14:48
	System	19 Oct 2020 17:14:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:38', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fa30aad3-8b0b-4881-8730-748f50922a0e' User entered 'No (N)'	System	19 Oct 2020 17:14:48
	System	19 Oct 2020 17:14:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fa30aad3-8b0b-4881-8730-748f50922a0e'	System	19 Oct 2020 17:14:48
User entered 'None (1)'	System	19 Oct 2020 17:14:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:43', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fa30aad3-8b0b-4881-8730-748f50922a0e' User entered '19 Oct 2020 12:14'	System	19 Oct 2020 17:14:48
	System	19 Oct 2020 17:14:48

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 6'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '72464d82-00c4-46a6-b141-63502a862a86'	System	20 Oct 2020 23:10:57
User entered 'None (1)'	System	20 Oct 2020 23:10:57

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:42', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '72464d82-00c4-46a6-b141-63502a862a86'	System	20 Oct 2020 23:10:57
User entered 'No (N)'	System	20 Oct 2020 23:10:57

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:46', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '72464d82-00c4-46a6-b141-63502a862a86'	System	20 Oct 2020 23:10:57
User entered 'No (N)'	System	20 Oct 2020 23:10:57

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '72464d82-00c4-46a6-b141-63502a862a86'	System	20 Oct 2020 23:10:57
User entered 'None (1)'	System	20 Oct 2020 23:10:57

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '72464d82-00c4-46a6-b141-63502a862a86' User entered '20 Oct 2020 18:10'	System	20 Oct 2020 23:10:57
	System	20 Oct 2020 23:10:57

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 7'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5a7a22b2-da63-4eee-8c55-f8ffd90cc6cb' User entered 'None (1)'	System	21 Oct 2020 20:02:29
	System	21 Oct 2020 20:02:29

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5a7a22b2-da63-4eee-8c55-f8ffd90cc6cb' User entered 'No (N)'	System	21 Oct 2020 20:02:29
	System	21 Oct 2020 20:02:29

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:22', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5a7a22b2-da63-4eee-8c55-f8ffd90cc6cb' User entered 'No (N)'	System	21 Oct 2020 20:02:29
	System	21 Oct 2020 20:02:29

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5a7a22b2-da63-4eee-8c55-f8ffd90cc6cb' User entered 'None (1)'	System	21 Oct 2020 20:02:29
	System	21 Oct 2020 20:02:29

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5a7a22b2-da63-4eee-8c55-f8ffd90cc6cb' User entered '21 Oct 2020 15:02'	System	21 Oct 2020 20:02:29
	System	21 Oct 2020 20:02:29

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:14', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'None (0)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:23', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'None (0)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'None (0)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'None (0)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'None (0)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:48', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'None (0)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:18:52', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered 'No (N)'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T12:19:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '07baef82-ab0a-4319-81bb-4434d030eeab' User entered '15 Oct 2020 12:19'	System	15 Oct 2020 17:19:03
	System	15 Oct 2020 17:19:03

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 12:08'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 14:38'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:53:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'None (0)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'None (0)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:06', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'None (0)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:09', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'None (0)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'None (0)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'None (0)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:25', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered 'No (N)'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-15T19:54:28', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '40f7b4ac-5bb0-4f9b-a80e-82b09ff399f0' User entered '15 Oct 2020 19:54'	System	16 Oct 2020 00:54:30
	System	16 Oct 2020 00:54:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '15 Oct 2020 15:33'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 2'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3'	System	16 Oct 2020 23:00:30
User entered 'No interference with activity (1)'	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:04', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered 'None (0)'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:08', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered 'None (0)'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:10', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered 'None (0)'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered 'None (0)'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:18', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered 'None (0)'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:21', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered 'No (N)'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-16T18:00:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '58debe9b-8cf9-4012-8b23-525332c3f2e3' User entered '16 Oct 2020 18:00'	System	16 Oct 2020 23:00:30
	System	16 Oct 2020 23:00:30

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 3'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:09', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered 'None (0)'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:11', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered 'None (0)'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered 'None (0)'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:18', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered 'None (0)'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered 'None (0)'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered 'None (0)'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3'	System	17 Oct 2020 18:53:37
User entered 'No (N)'	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-17T13:53:36', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '02fd7cc3-5499-47f7-a529-fd96c16a49e3' User entered '17 Oct 2020 13:53'	System	17 Oct 2020 18:53:37
	System	17 Oct 2020 18:53:37

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 4'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:50', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'None (0)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:52', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'None (0)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:55', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'None (0)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:42:59', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'None (0)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:43:04', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'None (0)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:43:08', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'None (0)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:43:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered 'No (N)'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-18T16:43:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '53b214cc-777c-4d13-8bd7-5aff0b760214' User entered '18 Oct 2020 16:43'	System	18 Oct 2020 21:43:20
	System	18 Oct 2020 21:43:20

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 5'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:47', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'None (0)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:49', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'None (0)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'None (0)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:53', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'None (0)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'None (0)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'None (0)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:14:59', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139' User entered 'No (N)'	System	19 Oct 2020 17:15:08
	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-19T12:15:02', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '27f3979c-534b-49d4-93c3-48cddcb1b139'	System	19 Oct 2020 17:15:08
User entered '19 Oct 2020 12:15'	System	19 Oct 2020 17:15:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 6'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:10:58', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered 'None (0)'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered 'None (0)'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:03', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered 'None (0)'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:05', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered 'None (0)'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered 'None (0)'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:09', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered 'None (0)'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:12', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024'	System	20 Oct 2020 23:11:18
User entered 'No (N)'	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-20T18:11:16', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '68096a3d-38f1-4c9a-b338-295165a1c024' User entered '20 Oct 2020 18:11'	System	20 Oct 2020 23:11:18
	System	20 Oct 2020 23:11:18

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	15 Oct 2020 16:53:13
User entered 'Day 7'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:51', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'None (0)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'None (0)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'None (0)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'None (0)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:01:59', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'None (0)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'None (0)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:03', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48' User entered 'No (N)'	System	21 Oct 2020 20:02:08
	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-10-21T15:02:06', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0189879d-e89f-48d0-bfab-68684119df48'	System	21 Oct 2020 20:02:08
User entered '21 Oct 2020 15:02'	System	21 Oct 2020 20:02:08

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 16:53:13

US3442173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:43:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 16:53:13

US3442173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:43:27

US3442173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:43:27

US3442173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:43:27

US3442173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 20:43:27

US3442173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 20:43:18

US3442173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	22 Oct 2020 20:43:18

US3442173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Oct 2020 17:07:51

US3442173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '29 Oct 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Oct 2020 17:07:51

US3442173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Oct 2020 17:07:51

US3442173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	29 Oct 2020 17:07:51

US3442173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Oct 2020 17:08:04

US3442173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	29 Oct 2020 17:08:04

US3442173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	05 Nov 2020 16:28:35

US3442173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '5 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	05 Nov 2020 16:28:35

US3442173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	05 Nov 2020 16:28:35

US3442173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	05 Nov 2020 16:28:35

US3442173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	05 Nov 2020 16:28:44

US3442173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	05 Nov 2020 16:28:44

US3442173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:07:57

US3442173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '9 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:07:57

US3442173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[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 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:07:57

US3442173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'VISIT3'	System	09 Nov 2020 19:07:57

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered empty.	System	09 Nov 2020 19:08:19

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34

US3442173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34

US3442173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:09:05

US3442173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:09:05

US3442173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:09:39

US3442173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '9 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:09:39

US3442173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12:30'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:09:39

US3442173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '9 Nov 2020 12:30'	System	09 Nov 2020 19:09:39

US3442173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 19:09:51

US3442173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered '1'	System	09 Nov 2020 19:09:51

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered 'Day 64'	System	16 Sep 2020 17:09:10

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-11-16T11:43:07', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '050e0e3f-48a2-4f5c-af3d-edc4379b0153'	System	16 Nov 2020 17:43:37
User entered 'No (N)'	System	16 Nov 2020 17:43:37

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-11-16T11:43:20', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '050e0e3f-48a2-4f5c-af3d-edc4379b0153'	System	16 Nov 2020 17:43:37
User entered 'No (N)'	System	16 Nov 2020 17:43:37

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-11-16T11:43:31', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '050e0e3f-48a2-4f5c-af3d-edc4379b0153' User entered '16 Nov 2020 11:43:31'	System	16 Nov 2020 17:43:37
	System	16 Nov 2020 17:43:37

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 17:09:10

US3442173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:47:54
Data entry locked.	System	16 Sep 2020 17:09:10
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 17:09:10

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-11-23T17:06:14', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd770b7d8-cb34-4706-949f-a87146211e21'	System	23 Nov 2020 23:06:36
User entered 'No (N)'	System	23 Nov 2020 23:06:36

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-11-23T17:06:27', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd770b7d8-cb34-4706-949f-a87146211e21'	System	23 Nov 2020 23:06:36
User entered 'No (N)'	System	23 Nov 2020 23:06:36

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-11-23T17:06:33', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd770b7d8-cb34-4706-949f-a87146211e21' User entered '23 Nov 2020 17:06:33'	System	23 Nov 2020 23:06:36
	System	23 Nov 2020 23:06:36

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-01T12:13:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd1acf090-95d5-4db7-b752-320b170ba3fb' User entered 'No (N)'	System	01 Dec 2020 18:14:21
	System	01 Dec 2020 18:14:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-01T12:14:13', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd1acf090-95d5-4db7-b752-320b170ba3fb' User entered 'No (N)'	System	01 Dec 2020 18:14:21
	System	01 Dec 2020 18:14:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-01T12:14:19', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd1acf090-95d5-4db7-b752-320b170ba3fb' User entered '01 Dec 2020 12:14:19'	System	01 Dec 2020 18:14:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-06T16:48:11', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '14eccde8-bc49-425b-95ef-49f29b68cf84' User entered 'No (N)'	System	06 Dec 2020 22:48:55
	System	06 Dec 2020 22:48:55

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-06T16:48:22', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '14eccde8-bc49-425b-95ef-49f29b68cf84'	System	06 Dec 2020 22:48:55
User entered 'Yes (Y)'	System	06 Dec 2020 22:48:55

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-06T16:48:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '14eccde8-bc49-425b-95ef-49f29b68cf84'	System	06 Dec 2020 22:48:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 22:48:55

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-06T16:48:46', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '14eccde8-bc49-425b-95ef-49f29b68cf84' User entered '06 Dec 2020 16:48:46'	System	06 Dec 2020 22:48:55
	System	06 Dec 2020 22:48:55

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-15T09:53:29', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c7dc1f03-f377-413f-918f-f474ef6922f7'	System	15 Dec 2020 15:54:14
User entered 'Yes (Y)'	System	15 Dec 2020 15:54:14

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-15T09:53:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c7dc1f03-f377-413f-918f-f474ef6922f7'	System	15 Dec 2020 15:54:14
User entered 'No (N)'	System	15 Dec 2020 15:54:14

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-15T09:53:57', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c7dc1f03-f377-413f-918f-f474ef6922f7'	System	15 Dec 2020 15:54:14
User entered 'No (N)'	System	15 Dec 2020 15:54:14

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-15T09:54:05', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c7dc1f03-f377-413f-918f-f474ef6922f7'	System	15 Dec 2020 15:54:14
User entered 'No (N)'	System	15 Dec 2020 15:54:14

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-15T09:54:10', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c7dc1f03-f377-413f-918f-f474ef6922f7' User entered '15 Dec 2020 09:54:10'	System	15 Dec 2020 15:54:14

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-19T17:00:03', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '129ab27b-f362-4e3e-b3a3-f995c7ce9f27'	System	19 Dec 2020 23:00:34
User entered 'No (N)'	System	19 Dec 2020 23:00:34

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-19T17:00:24', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '129ab27b-f362-4e3e-b3a3-f995c7ce9f27'	System	19 Dec 2020 23:00:34
User entered 'No (N)'	System	19 Dec 2020 23:00:34

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2020-12-19T17:00:31', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '129ab27b-f362-4e3e-b3a3-f995c7ce9f27' User entered '19 Dec 2020 17:00:31'	System	19 Dec 2020 23:00:34
	System	19 Dec 2020 23:00:34

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-04T12:12:19', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c71e9470-cd32-4903-9d1c-a51c6c84b34f' User entered 'No (N)'	System	04 Jan 2021 18:12:44
	System	04 Jan 2021 18:12:44

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-04T12:12:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c71e9470-cd32-4903-9d1c-a51c6c84b34f' User entered 'No (N)'	System	04 Jan 2021 18:12:44

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-04T12:12:42', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'c71e9470-cd32-4903-9d1c-a51c6c84b34f' User entered '04 Jan 2021 12:12:42'	System	04 Jan 2021 18:12:44
	System	04 Jan 2021 18:12:44

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-11T10:24:21', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0407eb22-9694-4139-b1b7-c8b2a191018f' User entered 'No (N)'	System	11 Jan 2021 16:25:00
	System	11 Jan 2021 16:25:00

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-11T10:24:54', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0407eb22-9694-4139-b1b7-c8b2a191018f' User entered 'No (N)'	System	11 Jan 2021 16:25:00

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-11T10:24:58', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '0407eb22-9694-4139-b1b7-c8b2a191018f' User entered '11 Jan 2021 10:24:58'	System	11 Jan 2021 16:25:00
	System	11 Jan 2021 16:25:00

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-18T18:44:29', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6871de74-dd83-4ca0-bccd-ace8b3f1d2a4' User entered 'No (N)'	System	19 Jan 2021 00:45:07
	System	19 Jan 2021 00:45:07

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-18T18:44:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6871de74-dd83-4ca0-bccd-ace8b3f1d2a4'	System	19 Jan 2021 00:45:07
User entered 'No (N)'	System	19 Jan 2021 00:45:07

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-18T18:45:01', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '6871de74-dd83-4ca0-bccd-ace8b3f1d2a4' User entered '18 Jan 2021 18:45:01'	System	19 Jan 2021 00:45:07
	System	19 Jan 2021 00:45:07

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-25T14:13:30', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '91e8aea4-63bb-4d44-994d-dc28035ce66c' User entered 'No (N)'	System	25 Jan 2021 20:14:17
	System	25 Jan 2021 20:14:17

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-25T14:13:37', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '91e8aea4-63bb-4d44-994d-dc28035ce66c' User entered 'No (N)'	System	25 Jan 2021 20:14:17
	System	25 Jan 2021 20:14:17

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-25T14:13:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '91e8aea4-63bb-4d44-994d-dc28035ce66c' User entered '25 Jan 2021 14:13:41'	System	25 Jan 2021 20:14:17
	System	25 Jan 2021 20:14:17

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-29T13:12:44', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '425ca1a5-5770-43ce-9292-696bf689c1e2' User entered 'No (N)'	System	29 Jan 2021 19:13:01
	System	29 Jan 2021 19:13:01

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-29T13:12:55', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '425ca1a5-5770-43ce-9292-696bf689c1e2' User entered 'No (N)'	System	29 Jan 2021 19:13:01
	System	29 Jan 2021 19:13:01

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-01-29T13:12:58', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '425ca1a5-5770-43ce-9292-696bf689c1e2' User entered '29 Jan 2021 13:12:58'	System	29 Jan 2021 19:13:01

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-02-09T08:10:56', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '099afc32-1f83-4746-8a30-891941a27858' User entered 'No (N)'	System	09 Feb 2021 14:11:51
	System	09 Feb 2021 14:11:51

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-02-09T08:11:41', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '099afc32-1f83-4746-8a30-891941a27858' User entered 'No (N)'	System	09 Feb 2021 14:11:51
	System	09 Feb 2021 14:11:51

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-02-09T08:11:47', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '099afc32-1f83-4746-8a30-891941a27858' User entered '09 Feb 2021 08:11:47'	System	09 Feb 2021 14:11:51
	System	09 Feb 2021 14:11:51

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-02-22T14:49:39', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9fd6a015-8c6f-4ece-8c47-8d6790204635'	System	22 Feb 2021 20:49:54
User entered 'No (N)'	System	22 Feb 2021 20:49:54

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-02-22T14:49:45', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9fd6a015-8c6f-4ece-8c47-8d6790204635'	System	22 Feb 2021 20:49:54
User entered 'No (N)'	System	22 Feb 2021 20:49:54

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-02-22T14:49:49', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9fd6a015-8c6f-4ece-8c47-8d6790204635' User entered '22 Feb 2021 14:49:49'	System	22 Feb 2021 20:49:54
	System	22 Feb 2021 20:49:54

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-01T18:13:10-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '22481121-b9da-4eb0-8cd3-9703c040c41d'	System	02 Mar 2021 00:16:21
User entered 'No (N)'	System	02 Mar 2021 00:16:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-01T18:13:16-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '22481121-b9da-4eb0-8cd3-9703c040c41d'	System	02 Mar 2021 00:16:21
User entered 'No (N)'	System	02 Mar 2021 00:16:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-01T18:13:19-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '22481121-b9da-4eb0-8cd3-9703c040c41d'	System	02 Mar 2021 00:16:21
User entered '01 Mar 2021 18:13:19'	System	02 Mar 2021 00:16:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-12T09:49:54-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5ad7a15e-d317-4a55-90a1-844758b50d88'	System	12 Mar 2021 15:50:05
User entered 'No (N)'	System	12 Mar 2021 15:50:05

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-12T09:49:59-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5ad7a15e-d317-4a55-90a1-844758b50d88'	System	12 Mar 2021 15:50:05
User entered 'No (N)'	System	12 Mar 2021 15:50:05

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-12T09:50:03-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5ad7a15e-d317-4a55-90a1-844758b50d88' User entered '12 Mar 2021 09:50:03'	System	12 Mar 2021 15:50:05
	System	12 Mar 2021 15:50:05

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-23T12:18:46-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fab6184f-dd1b-4c75-8108-81c255c4bf08'	System	23 Mar 2021 17:19:08
User entered 'No (N)'	System	23 Mar 2021 17:19:08

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-23T12:18:52-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fab6184f-dd1b-4c75-8108-81c255c4bf08'	System	23 Mar 2021 17:19:08
User entered 'No (N)'	System	23 Mar 2021 17:19:08

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-23T12:19:05-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'fab6184f-dd1b-4c75-8108-81c255c4bf08'	System	23 Mar 2021 17:19:08
User entered '23 Mar 2021 12:19:05'	System	23 Mar 2021 17:19:08

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-27T12:14:39-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '394b8e32-000a-469b-84f8-208a8b1a9851' User entered 'No (N)'	System	27 Mar 2021 17:14:50
	System	27 Mar 2021 17:14:50

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-27T12:14:43-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '394b8e32-000a-469b-84f8-208a8b1a9851'	System	27 Mar 2021 17:14:50
User entered 'No (N)'	System	27 Mar 2021 17:14:50

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-27T12:14:48-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '394b8e32-000a-469b-84f8-208a8b1a9851' User entered '27 Mar 2021 12:14:48'	System	27 Mar 2021 17:14:50
	System	27 Mar 2021 17:14:50

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-12T17:59:30-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd624499f-51a8-49aa-b881-9547c6a4ccf4' User entered 'No (N)'	System	12 Apr 2021 22:59:47
	System	12 Apr 2021 22:59:47

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-12T17:59:37-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd624499f-51a8-49aa-b881-9547c6a4ccf4'	System	12 Apr 2021 22:59:47
User entered 'No (N)'	System	12 Apr 2021 22:59:47

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-12T17:59:41-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'd624499f-51a8-49aa-b881-9547c6a4ccf4' User entered '12 Apr 2021 17:59:41'	System	12 Apr 2021 22:59:47
	System	12 Apr 2021 22:59:47

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-19T18:04:29-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5f9d2720-1eb8-42a3-af08-90ca13dff1af' User entered 'No (N)'	System	19 Apr 2021 23:05:21
	System	19 Apr 2021 23:05:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-19T18:04:33-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5f9d2720-1eb8-42a3-af08-90ca13dff1af'	System	19 Apr 2021 23:05:21
User entered 'No (N)'	System	19 Apr 2021 23:05:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-19T18:04:37-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '5f9d2720-1eb8-42a3-af08-90ca13dff1af' User entered '19 Apr 2021 18:04:37'	System	19 Apr 2021 23:05:21
	System	19 Apr 2021 23:05:21

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-25T12:00:55-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e18a613d-eb93-47fa-8728-54cc19cc6d89' User entered 'No (N)'	System	25 Apr 2021 17:01:46
	System	25 Apr 2021 17:01:46

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-25T12:00:57-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e18a613d-eb93-47fa-8728-54cc19cc6d89'	System	25 Apr 2021 17:01:46
User entered 'No (N)'	System	25 Apr 2021 17:01:46

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-04-25T12:01:01-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: 'e18a613d-eb93-47fa-8728-54cc19cc6d89' User entered '25 Apr 2021 12:01:01'	System	25 Apr 2021 17:01:46
	System	25 Apr 2021 17:01:46

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-05-02T12:00:18-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '968a66d7-551f-46b8-b873-b71579803255'	System	02 May 2021 17:00:42
User entered 'No (N)'	System	02 May 2021 17:00:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

Have you been exposed to someone with 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 (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-05-02T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '968a66d7-551f-46b8-b873-b71579803255'	System	02 May 2021 17:00:42
User entered 'No (N)'	System	02 May 2021 17:00:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-05-02T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '968a66d7-551f-46b8-b873-b71579803255'	System	02 May 2021 17:00:42
User entered '02 May 2021 12:00:29'	System	02 May 2021 17:00:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 08:55:42

US3442173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:42
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 08:55:42

US3442173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:12

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)	26 Apr 2021 07:59:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-01T18:13:34-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9e2ac9cf-0010-43dd-860e-0db5cb971513'	System	02 Mar 2021 00:16:42
User entered 'No (N)'	System	02 Mar 2021 00:16:42

US3442173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:59:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (15CD1524-CEA9-413A-8E47-DD00A65BDBCD)', Time: '2021-03-01T18:13:42-06:00', User OID: 'PatientReportedOutcome (US3442173)', ODM File OID: '9e2ac9cf-0010-43dd-860e-0db5cb971513' User entered '01 Mar 2021 18:13:42'	System	02 Mar 2021 00:16:42
	System	02 Mar 2021 00:16:42

US3442173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:13:00

US3442173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '7 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:13:00

US3442173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:13:00

US3442173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:13:00

US3442173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:13:39

US3442173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:58:34
User entered 'I'	System	08 Dec 2020 02:13:39

US3442173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:37:59

US3442173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:37:59

US3442173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:37:59

US3442173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 22:37:59

US3442173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:37:53

US3442173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User entered 'I'	System	04 Feb 2021 22:37:53

US3442173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:58

US3442173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:58

US3442173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:58

US3442173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:58

US3442173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:51:06

US3442173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User entered '1'	System	12 Feb 2021 21:51:06

US3442173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	11 Mar 2021 21:00:04

US3442173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '11 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	11 Mar 2021 21:00:04

US3442173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	11 Mar 2021 21:00:04

US3442173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	11 Mar 2021 21:00:04

US3442173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	11 Mar 2021 21:00:11

US3442173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:46:22
User entered '1'	System	11 Mar 2021 21:00:11

US3442173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:03

US3442173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered '30 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:03

US3442173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:03

US3442173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 20:33:03

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 20:33:10

US3442173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:37

US3442173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:37

US3442173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:52

US3442173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered '30 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:52

US3442173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered '11:50'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:33:52

US3442173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 11:50'	System	30 Mar 2021 20:33:52

US3442173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	30 Mar 2021 20:34:01

US3442173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 20:34:01

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:12

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:52:26
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:23:48

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:12

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:52:26
User entered '09:52'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:23:48

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:12

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:31
User entered '7 Dec 2020 09:52'	System	08 Dec 2020 02:23:48

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:12

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:52:26
User entered 'Safety Call (Safety Call)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:23:48

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:12

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:31
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:52:26
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:23:48

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 1 (Day 1)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:06
User entered '4 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:32:35
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Per CDM re-query: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 09:23:15
Query 'Per CDM re-query: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	03 Feb 2021 19:11:23
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:11:15
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:11:15
User opened query 'Per CDM re-query: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:04:27
User closed query 'Per CDM: Assessment Not Done is checked yet data is present for days 1- 3. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:04:27
Query 'Per CDM: Assessment Not Done is checked yet data is present for days 1- 3. Please review and reconcile.' answered with 'symptoms on log were reported by subject prior to illness day 1. Assessments were not yet initiated.' (Site from DM).	Alma Guel (b) (4)	22 Jan 2021 20:25:23
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:56:07
User opened query 'Per CDM: Assessment Not Done is checked yet data is present for days 1- 3. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 01:11:07
User entered '1'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:32:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
	Alma Guel (b) (4)	03 Feb 2021 19:11:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:11:15
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:56:19
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	03 Feb 2021 19:11:15
User entered empty.	System	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:32:38
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for	Alma Guel (b) (4)	03 Feb 2021 19:11:15
change Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:11:15
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:56:20
User entered empty.	Oluwatosin Akingbala	08 Dec 2020 02:27:55
	(b) (4)	

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:37
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:40
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:42
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:44
User entered 'None (None)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:28:13
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:46
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:49
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:56:54
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:01
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:02
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:09
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:10
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:11
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:13
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:14
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:15
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:27:55

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 2 (Day 2)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:19
User entered '5 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:32:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' (Site from DM). Query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 09:23:27
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:16:28
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:11:39
User opened query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 13:05:29
User entered '1'	(b) (4), (b) (6)	22 Jan 2021 17:57:20
	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:32:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for	Alma Guel (b) (4)	03 Feb 2021 19:11:39
change Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:11:39
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:57:21
User entered empty.	Oluwatosin Akingbala	08 Dec 2020 18:35:20
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	03 Feb 2021 19:11:39
User entered empty.	System	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:32:44
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for	Alma Guel (b) (4)	03 Feb 2021 19:11:39
change Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:11:39
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:57:23
User entered empty.	Oluwatosin Akingbala	08 Dec 2020 18:35:20
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:25
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:57:27
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:12
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:14
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:17
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:18
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:21
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:40:51
Query ' Subject did not have any symptoms. Headache ended on 04Dec2020. Please change the response. ' canceled (Site from CRA).		07 Apr 2021 17:40:50
User opened query ' Subject did not have any symptoms. Headache ended on 04Dec2020. Please change the response. ' (Site from CRA).		07 Apr 2021 17:38:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
	(b) (4)	
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 20:24:07
User entered 'Mild (Mild)' reason for change: Data	Alma Guel (b) (4)	22 Jan 2021 20:24:07
Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:58:26
User entered 'None (None)'	Oluwatosin Akingbala	08 Dec 2020 18:35:20
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:28
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:31
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:35
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:37
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:38
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:40
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:41
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:35:20

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 3 (Day 3)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:58:57
User entered '6 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:32:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' (Site from DM). Query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 09:23:38
Query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	03 Feb 2021 19:18:04
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:17:55
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:17:55
User opened query 'Per CDM: 'Assessment Not Done' should only be checked if no Symptoms were assessed for this day. Any symptoms not assessed should be recorded individually as 'Not Done'. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:05:40
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:58:59
User entered '1'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:32:48
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for	Alma Guel (b) (4)	03 Feb 2021 19:17:55
change Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:17:55
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:59:00
User entered empty.	Oluwatosin Akingbala	08 Dec 2020 18:39:38
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	03 Feb 2021 19:17:55
User entered empty.	System	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:32:50
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:17:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:17:55
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:59:01
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:03
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:17
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:20
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:22
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:23
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:25
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:29
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:41:00
Query ' Subject did not have any symptoms. Headache ended on 04Dec2020. Please change the response. ' canceled (Site from CRA).		07 Apr 2021 17:40:59
User opened query ' Subject did not have any symptoms. Headache ended on 04Dec2020. Please change the response. ' (Site from CRA).		07 Apr 2021 17:38:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
	(b) (4)	
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 20:24:07
User entered 'Mild (Mild)' reason for change: Data	Alma Guel (b) (4)	22 Jan 2021 20:24:07
Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 17:59:32
User entered 'None (None)'	Oluwatosin Akingbala	08 Dec 2020 18:39:38
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:33
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:38
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:40
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:41
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:42
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:43
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:45
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:39:38

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 4 (Day 4)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:53
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:55
User entered '0'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:59:58
User entered '96'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:08
User entered '96.8' F	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:14
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:16
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:18
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:22
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:23
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:36:41
DataPoint Un-verified.		07 Apr 2021 17:35:47
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:25
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
DataPoint Verified.		07 Apr 2021 17:41:08
Query 'Subject did not have any symptoms. Headache ended on 04Dec2020. Please change the response. ' canceled (Site from CRA). User opened query 'Subject did not have any symptoms. Headache ended on 04Dec2020. Please change the response. ' (Site from CRA). User signature succeeded.		07 Apr 2021 17:41:06 07 Apr 2021 17:37:11
	William Seger (b) (4) (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 20:24:07
User entered 'Mild (Mild)' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 20:24:07
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:00:29
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:31
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:33
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:36
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:38
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:39
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:41
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:42
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:00:44
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:45:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 5 (Day 5)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:15
User entered '8 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:17
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:20
User entered '96'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:39:06

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:24
User entered '99.1' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:29
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:30
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:36
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:45
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:47
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:48
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:49
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:51
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:53
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:57
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:14:59
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:15:01
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:15:03
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:15:05
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:39:06

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 6 (Day 6)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:00
User entered '9 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:01
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:03
User entered '96'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:04
User entered '99.0' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:06
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:10
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:16
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:20
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:21
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:23
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:25
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:29
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:32
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:36
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:38
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:20:39
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:44:34

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 7 (Day 7)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:33
User entered '10 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:34
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:35
User entered '96'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:44
User entered '98.7' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:48
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:49
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:50
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:54
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:56
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:21:58
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:02
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:04
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:08
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:12
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:14
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:16
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:20
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:22:22
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:46:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 8 (Day 8)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:02
User entered '11 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:03
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:05
User entered '97'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:17
User entered '98.6' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:27
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:29
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:31
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:36
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:37
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:40
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:42
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:43
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:45
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:23:47
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:48
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:49
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:23:51
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:48:44

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 9 (Day 9)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:13
User entered '12 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:16
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:19
User entered '92'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:47
User entered '98.7' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:54
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:56
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:57
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:59
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:01
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:03
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:05
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:06
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:08
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:09
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:12
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:14
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:15
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:25:20
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:50:31

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 10 (Day 10)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:04
User entered '13 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:06
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:08
User entered '96'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:23
User entered '97.9' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:37
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:39
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:40
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:41
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:43
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:46
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:47
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:48
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:50
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:52
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:53
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:54
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:56
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:58
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:52:58

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 11 (Day 11)'	(b) (4) Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:29:41
User entered '14 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:29:42
User entered '0'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:29:49
User entered '95'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:03
User entered '98.8' F	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:08
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:09
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:11
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:13
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:14
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:16
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:20
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:22
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:23
User entered 'Mild (Mild)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:25
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:26
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:28
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:29
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:54:59

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 12 (Day 12)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:45
User entered '15 Dec 2020'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:46
User entered '0'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:48
User entered '92'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:30
User entered '97.7' F	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:37
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:38
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:40
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:41
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:42
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:44
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:31:46
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:47
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:48
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:50
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:51
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:53
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:54
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:55
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:31:57
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:14:15

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 13 (Day 13)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:03
User entered '16 Dec 2020'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:04
User entered '0'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:05
User entered '96'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:12
User entered '97.9' F	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:15
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:16
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:18
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:21
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:22
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:23
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:25
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:26
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:28
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:31
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:32
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:34:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:35
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:37
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:16:53

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 14 (Day 14)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:49
User entered '17 Dec 2020'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:50
User entered '0'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:34:52
User entered '96'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:21
User entered '97.9' F	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:27
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:29
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:32
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:33
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:36
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:39
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:40
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:41
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:43
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:45
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:46
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:47
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:49
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:35:50
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:18:33

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 15 (Day 15)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:36:01
User entered '18 Dec 2020'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:36:02
User entered '0'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:36:05
User entered '96'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:37:55
User entered '97.5' F	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:37:59
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:00
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:02
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:04
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:05
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:06
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:07
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:09
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:10
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:11
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:14
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:15
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:18
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:20
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:21
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:21:12

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Day 16 (Day 16)'	(b) (4) Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:31
User entered '19 Dec 2020'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:33
User entered '0'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:38:56
User entered '96'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:39:02
User entered '98.0' F	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:39:03
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:39:05
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:39:07
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:15
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:21
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:22
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:23
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:25
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:27
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:31
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:33
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:34
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:36
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:24:40

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User closed query 'Per CDM: Per sponsor review, please verify data and consider updating Symptom Day to 'Day 17' on this form. ' (Site from DM).	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 10:51:05
	John Villegas (b) (4)	19 Mar 2021 18:10:57
	(b) (4)	
User entered 'Day 17 (Day 17)' reason for change:	John Villegas (b) (4)	19 Mar 2021 18:10:57
Data Entry Error	(b) (4)	
Query 'Per CDM: Per sponsor review, please verify data and consider updating Symptom Day to 'Day 17' on this form. ' answered with 'updated' (Site from DM).	John Villegas (b) (4)	19 Mar 2021 18:10:50
	(b) (4)	
User opened query 'Per CDM: Per sponsor review, please verify data and consider updating Symptom Day to 'Day 17' on this form. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 21:35:50
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
	(b) (4)	
User entered 'Day 18 (Day 18)'	Oluwatosin Akingbala	29 Dec 2020 21:27:29
	(b) (4)	

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:54
User entered '20 Dec 2020'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:56
User entered '0'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:57
User entered '96'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User entered '%'	System	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:49:49
User entered '97.7' F	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:05
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:06
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:08
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:09
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:11
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:13
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:14
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:17
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:19
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:21
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:22
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:24
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:25
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:27
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:28
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:12

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:50:30
User entered 'None (None)'	Oluwatosin Akingbala (b) (4)	29 Dec 2020 21:27:29

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:54:56
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[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 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:08
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[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 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 11:10:04
User closed query 'Subject test results came out as +ve on 11Dec2020. Please change the response to YES. ' (Site from CRA).		22 Jan 2021 20:48:44
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed positive result. ae updated' (Site from System).	Alma Guel (b) (4)	22 Jan 2021 20:21:23
Query 'Subject test results came out as +ve on 11Dec2020. Please change the response to YES. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	22 Jan 2021 20:20:57
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	22 Jan 2021 20:20:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 20:20:51
User opened query 'Subject test results came out as +ve on 11Dec2020. Please change the response to YES. ' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 17:54:53
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:12
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:14
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:15
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

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 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:17
User entered 'No (N)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:52:20
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	08 Dec 2020 18:49:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:41
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	08 Dec 2020 18:49:04
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:19
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 18:52:20
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 18:49:41
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:55:20
User entered empty; reason for change Data Entry Error	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:52:20
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:12

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:45:52
User entered '1'	System	22 Jan 2021 20:20:51
User entered '0'	System	08 Dec 2020 18:49:04

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
DataPoint Verified.		07 Apr 2021 17:41:51
User closed query 'Please revisit response as an 02 sat of 92% was noted on 12Dec2020 and 15Dec2020.' (Site from CRA).		07 Apr 2021 17:41:45
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
	(b) (4)	
Query 'Please revisit response as an 02 sat of 92% was noted on 12Dec2020 and 15Dec2020.' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	03 Feb 2021 19:23:57
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:23:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:23:47
User opened query 'Please revisit response as an 02 sat of 92% was noted on 12Dec2020 and 15Dec2020.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 23:10:41
DataPoint Verified.		22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
DataPoint Verified.		07 Apr 2021 17:41:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
	Alma Guel (b) (4)	03 Feb 2021 19:24:41
User entered '12 Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:24:41
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:09:30
User closed query 'Please consider changing the response as subject had low o2 on 2 occasions 12Dec2020 & 15Dec2020 therefore the end date would be 16Dec2020. If you would like to use 13Dec2020 as the end date please clarify. ' (Site from CRA).		07 Apr 2021 22:09:28
Query 'Please consider changing the response as subject had low o2 on 2 occasions 12Dec2020 & 15Dec2020 therefore the end date would be 16Dec2020. If you would like to use 13Dec2020 as the end date please clarify. ' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	07 Apr 2021 22:09:03
Signature has been broken.	Alma Guel (b) (4)	07 Apr 2021 22:08:55
User entered '15 Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	07 Apr 2021 22:08:55
User opened query 'Please consider changing the response as subject had low o2 on 2 occasions 12Dec2020 & 15Dec2020 therefore the end date would be 16Dec2020. If you would like to use 13Dec2020 as the end date please clarify. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:43:41
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:24:41
User entered '13 Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:24:41
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
DataPoint Verified.		07 Apr 2021 17:43:43
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Un-verified.	(b) (4)	
	Alma Guel (b) (4)	03 Feb 2021 19:24:41
User entered '92' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Feb 2021 19:24:41
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

US3442173

Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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Folder: Covid-19 Assessment 07 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:12

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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[Start Date](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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Folder: Covid-19 Assessment 07 Dec 2020

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
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Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
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[Evidence of Shock Requires
Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:35:42

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[Neurologic Dysfunction?](#)

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User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
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[Clinical Evidence](#)

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:00
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:48:33
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Folder: Covid-19 Assessment 07 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:43:12

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:08
DataPoint Verified.		07 Apr 2021 17:44:07
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 22:38:10

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:55:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:16:38
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:55:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:16:40
User entered '9 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:55:51

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:57:41

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:00
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:57:41

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:24:02
User entered '11 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:57:41

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:58:06

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:13
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:58:06

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:26:15
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		29 Dec 2020 06:21:26
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:31
' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:45:38
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 15DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		
User entered '13 Dec 2020'	Oluwatosin Akingbala (b) (4)	15 Dec 2020 18:58:06

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:57
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:30:59
User entered '15 Dec 2020'	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:50
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:41:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 21:41:02
User entered 'Yes (Y)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:41:02
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:39:58
User entered empty.	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:48:51
User entered '20 Dec 2020' reason for change: Data Entry Error	John Villegas (b) (4)	28 Dec 2020 21:41:02
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:53:22
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Jan 2021 20:28:11
User closed query 'Data is required. Please complete.' (Site from System).		04 Jan 2021 14:01:47
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:41:19
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:39:58
User entered empty.	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Data of collection should be 27Dec2020. Please change the response as applicable. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:44:53
		07 Apr 2021 17:44:52
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
	(b) (4)	
User entered '27 Dec 2020' reason for change: Data Entry Error	John Villegas (b) (4)	26 Jan 2021 18:13:29
	(b) (4)	
Query 'Data of collection should be 27Dec2020. Please change the response as applicable. ' answered with 'updated' (Site from CRA).	John Villegas (b) (4)	26 Jan 2021 18:13:21
	(b) (4)	
User opened query 'Data of collection should be 27Dec2020. Please change the response as applicable. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 18:55:31
		22 Jan 2021 18:54:43
DataPoint Verified.		22 Jan 2021 18:53:24
User entered '5 Jan 2021' reason for change: Data Entry Error		05 Jan 2021 20:28:11
User entered empty.	John Villegas (b) (4)	28 Dec 2020 21:39:58
	(b) (4)	

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:12

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	John Villegas (b) (4) (b) (4)	28 Dec 2020 21:39:58

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:12

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:03
User closed query 'D28 visit is completed on 05Jan2021. Please update the field as YES. ' (Site from CRA).		07 Apr 2021 17:45:02
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
Query 'D28 visit is completed on 05Jan2021. Please update the field as YES. ' answered with 'updated' (Site from CRA).	John Villegas (b) (4)	26 Jan 2021 18:13:48
	(b) (4)	
Query 'D28 visit is completed on 05Jan2021. Please update the field as YES. ' answered with 'updated' (Site from CRA).	John Villegas (b) (4)	26 Jan 2021 18:13:40
	(b) (4)	
User opened query 'D28 visit is completed on 05Jan2021. Please update the field as YES. ' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 18:56:12
User closed query 'Data is required. Please complete.' (Site from System).		04 Jan 2021 14:01:49
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	John Villegas (b) (4)	28 Dec 2020 21:41:28
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:39:58
User entered empty.	John Villegas (b) (4)	28 Dec 2020 21:39:58
	(b) (4)	

US3442173

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:05
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 18:13:48
User entered empty.	John Villegas (b) (4)	28 Dec 2020 21:39:58
	(b) (4)	

US3442173

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:01:09
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:06:40

US3442173

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:01:09
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:06:40

US3442173

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[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 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:01:09
User entered 'Clinic (Clinic)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:06:40

US3442173

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User entered 'SICKD1'	System	08 Dec 2020 02:06:40

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '13:38'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User entered '7 Dec 2020 13:38'	System	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '65.0' in	Oluwatosin Akingbala	08 Dec 2020 02:08:54
DataPoint set to visible.	(b) (4) System	08 Dec 2020 02:06:40

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '203.0' lb	Oluwatosin Akingbala	08 Dec 2020 02:08:54
DataPoint set to visible.	(b) (4) System	08 Dec 2020 02:06:40

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '96.8' F	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered 'Oral (Oral)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered empty.	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '69'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User entered 'bpm'	System	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '12'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User entered 'breaths/min'	System	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '138'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User entered 'mmHg'	System	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:02:08
User entered '79'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User entered 'mmHg'	System	08 Dec 2020 02:08:54

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55

US3442173

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55

US3442173

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:06:52
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:09:30

US3442173

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:06:52
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:09:30

US3442173

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:12

[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 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:12:36
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:09:59

US3442173

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:30:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 18:12:36
User entered '7 Dec 2020'	Oluwatosin Akingbala (b) (4)	08 Dec 2020 02:09:59

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:01:36
User entered 'Yes (Y)'		05 Jan 2021 20:24:08

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:01:36
User entered '5 Jan 2021'		05 Jan 2021 20:24:08

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:01:36
User entered 'Clinic (Clinic)'		05 Jan 2021 20:24:08

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:32
User entered 'SICKD28'	System	05 Jan 2021 20:24:08

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered 'Yes (Y)'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '5 Jan 2021'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '13:39'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User entered '5 Jan 2021 13:39'	System	05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '65.0' in		05 Jan 2021 20:26:19
DataPoint set to visible.	System	05 Jan 2021 20:24:08

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '202.8' lb		05 Jan 2021 20:26:19
DataPoint set to visible.	System	05 Jan 2021 20:24:08

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '97.9' F		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered 'Oral (Oral)'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered empty.		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '65'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User entered 'bpm'	System	05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '16'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User entered 'breaths/min'	System	05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '118'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User entered 'mmHg'	System	05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:10
User entered '80'		05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36
User entered 'mmHg'	System	05 Jan 2021 20:26:19

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:36

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:23
User entered 'Yes (Y)'		05 Jan 2021 20:26:42

US3442173

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:23
User entered '5 Jan 2021'		05 Jan 2021 20:26:42

US3442173

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:43:12

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:43
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:25
User entered 'Yes (Y)'		05 Jan 2021 20:27:07

US3442173

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:43:12

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:43
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 19:03:25
User entered '5 Jan 2021'		05 Jan 2021 20:27:07

US3442173

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:10:53

US3442173

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 00:13:51
User entered '12 Jan 2021'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:10:53

US3442173

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:10:53

US3442173

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

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 00:10:53

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:14:09
User entered '12 Jan 2021'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:09:50

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:09:50

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 00:14:09
User entered '12 Jan 2021'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Placebo (Placebo)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:48:38
User entered 'Placebo (Placebo)'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:48:38
User entered 'Placebo (Placebo)'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '1'	System	13 Jan 2021 00:11:28

US3442173

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

Form: Unblinding

Generated On: 11 Aug 2021 22:43:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '1'	System	13 Jan 2021 00:11:28

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered empty.	System	13 Jan 2021 00:13:02
DataPoint set to visible.	System	13 Jan 2021 00:11:28

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered empty.	System	13 Jan 2021 00:13:02
DataPoint set to visible.	System	13 Jan 2021 00:11:28

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User accepted default value 'Pre-Dose (PREDOSE)'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	13 Jan 2021 00:13:51
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Jan 2021 00:13:02
User entered '11 Jan 2021'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '09:36'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '11 Jan 2021 09:36'	System	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '98.4' F	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '73'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'bpm'	System	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '13'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'breaths/min'	System	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '110'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '73'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:13:02

US3442173

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered empty.	System	13 Jan 2021 00:13:02
DataPoint set to visible.	System	13 Jan 2021 00:11:28

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User accepted default value 'Post-Dose (POSTDOSE)'	Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11:18'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '11 Jan 2021 11:18'	System	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '98.1' F	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '66'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'bpm'	System	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '14'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'breaths/min'	System	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '117'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '83'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:15:59

US3442173

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	13 Jan 2021 00:15:59

US3442173

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:16:20

US3442173

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:16:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:17:20

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

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)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mRNA-1273'	System	13 Jan 2021 00:17:20
DataPoint set to visible.	System	13 Jan 2021 00:11:28

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '10:38'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '11 Jan 2021 10:38'	System	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'ONCE'	System	13 Jan 2021 00:17:20

US3442173

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

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 00:17:20

US3442173

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:27

US3442173

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:27

US3442173

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '09:42'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:27

US3442173

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '11 Jan 2021 09:42'	System	13 Jan 2021 00:18:27

US3442173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:48

US3442173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '11 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:48

US3442173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '09:39'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:48

US3442173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '11 Jan 2021 09:39'	System	13 Jan 2021 00:18:48

US3442173

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

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 00:18:56

US3442173

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

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '1'	System	13 Jan 2021 00:18:56

US3442173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:34:05

US3442173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:34:05

US3442173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:34:05

US3442173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:34:05

US3442173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:34:13

US3442173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'I'	System	20 Jan 2021 01:34:13

US3442173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '1'	System	20 Jan 2021 01:34:13
DataPoint set to visible.	System	20 Jan 2021 01:34:13

US3442173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:26:19

US3442173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:26:19

US3442173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:26:19

US3442173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'OLD29'	System	06 Feb 2021 14:26:19

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User accepted default value 'Pre-Dose (PREDOSE)'	Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '09:25'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '5 Feb 2021 09:25'	System	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 19:12:45
User entered '98.7' F	Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '66'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'bpm'	System	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '14'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'breaths/min'	System	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '124'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '85'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	06 Feb 2021 14:27:03

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User accepted default value 'Post-Dose (POSTDOSE)'	Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '10:16'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '5 Feb 2021 10:16'	System	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '98.3' F	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '59'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'bpm'	System	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '12'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'breaths/min'	System	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '106'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '72'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	06 Feb 2021 14:28:04

US3442173

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:16

US3442173

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:16

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

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)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mRNA-1273'	System	06 Feb 2021 14:28:44
DataPoint set to visible.	System	20 Jan 2021 01:34:13

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '09:44'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '5 Feb 2021 09:44'	System	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'ONCE'	System	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'INTRAMUSCULAR'	System	06 Feb 2021 14:28:44

US3442173

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	06 Feb 2021 14:29:13

US3442173

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '1'	System	06 Feb 2021 14:29:13

US3442173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:18

US3442173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '12 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:18

US3442173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:18

US3442173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:12

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:18

US3442173

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Feb 2021 21:50:26

US3442173

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '1'	System	12 Feb 2021 21:50:26

US3442173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:59:29

US3442173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '2 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:59:29

US3442173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:59:29

US3442173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'OLD57'	System	03 Mar 2021 00:59:29

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '2 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '14:46'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '2 Mar 2021 14:46'	System	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '98.1' F	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '82'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'bpm'	System	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '16'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'breaths/min'	System	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '105'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '75'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered 'mmHg'	System	03 Mar 2021 01:01:35

US3442173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14

US3442173

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:52

US3442173

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:12

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '2 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:01:52

US3442173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:02:39

US3442173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '2 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:02:39

US3442173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '14:55'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:02:39

US3442173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:14
User entered '2 Mar 2021 14:55'	System	03 Mar 2021 01:02:39

US3442173

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:43:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:34:59
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Subject was COVID +ve. Please update AE page. ' (Site from CRA).	(b) (4)	
Query 'Subject was COVID +ve. Please update AE page. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 20:48:53
User opened query 'Subject was COVID +ve. Please update AE page. ' (Site from CRA).	Alma Guel (b) (4)	22 Jan 2021 20:20:29
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 19:06:30
User entered 'Yes (Y)' reason for change: Data Entry Error		22 Jan 2021 19:05:25
User entered 'No (N)'		10 Nov 2020 21:40:22
		16 Sep 2020 18:24:47

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Fractured toe - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 21:54:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 21:54:40
Data point term sent to Coder	System	10 Nov 2020 21:44:19
User entered 'broken toes: right 3rd and 4th'	(b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User entered empty.	System	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 04:21:59
User entered 'No (N)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	02 Dec 2020 17:15:57
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	John Villegas (b) (4) (b) (4)	02 Dec 2020 17:12:56
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:39:51
User entered 'Yes (Y)'		10 Nov 2020 21:44:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 04:21:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	John Villegas (b) (4) (b) (4)	02 Dec 2020 17:16:07
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Dec 2020 17:15:57
User entered '16 Nov 2020' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	02 Dec 2020 17:15:57
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:44:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User entered empty.	System	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4) (b) (4)	18 Mar 2021 21:46:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	02 Dec 2020 17:16:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User entered '0'	System	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06
User entered '0'	System	10 Nov 2020 21:44:13

US3442173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:12

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:41:06

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:43
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 23:58:25
User entered 'USA-US017-2021-mRNA-1273-P301000007'	System	25 Jan 2021 23:58:15
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 23:58:15

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:00
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)	22 Jan 2021 20:22:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 20:22:04
Data point term sent to Coder	System	22 Jan 2021 20:21:05
User entered 'Covid-19'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:01
User entered 'Yes (Y)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:03
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:04
User entered 'Yes (Y)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:06
User entered '04 Dec 2020'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:07
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:09
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:10
User entered '15 Dec 2020'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:12
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:14
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:17
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:18
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:23
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:25
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:26
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:27
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:29
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:31
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:32
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:33
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:25
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User closed query 'Per CDM: AE start date is after first dose and Relationship to IP is reported as Not Applicable. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:51:42
Query 'Per CDM: AE start date is after first dose and Relationship to IP is reported as Not Applicable. Please review and update. ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	03 Feb 2021 19:10:35
DataPoint Un-verified.	Alma Guel (b) (4)	03 Feb 2021 19:10:26
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	03 Feb 2021 19:10:26
reason for change: Data Entry Error		
User opened query 'Per CDM: AE start date is after first dose and Relationship to IP is reported as Not Applicable. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:16:33
DataPoint Verified.		22 Jan 2021 20:49:34
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:46:27
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User closed query 'Per CDM: AE start date is after first dose and Relationship to Study Procedure is reported as Not Applicable. Please review and update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:14:08
Query 'Per CDM: AE start date is after first dose and Relationship to Study Procedure is reported as Not Applicable. Please review and update. ' answered with 'updated ' (Site from DM).	Alma Guel (b) (4)	04 Feb 2021 13:59:55
DataPoint Un-verified.	Alma Guel (b) (4)	04 Feb 2021 13:59:40
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	04 Feb 2021 13:59:40
reason for change: Data Entry Error		
User opened query 'Per CDM: AE start date is after first dose and Relationship to Study Procedure is reported as Not Applicable. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:52:32
DataPoint Verified.		22 Jan 2021 20:49:35
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:37
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:39
User entered 'I'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:21:12
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment provided' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:15:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 20:28:00
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:49:40
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:41
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 20:49:44
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User closed query 'PV Query: On days 12 Dec 2020 and 15 Dec 2020, oxygenation saturation was reported to be 92%. COVID severity assessment reports the subject 's oxygenation saturation did not exceed 93% or below. Please reconcile.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:21:17
Query 'PV Query: On days 12 Dec 2020 and 15 Dec 2020, oxygenation saturation was reported to be 92% COVID severity assessment reports the subject 's oxygenation saturation did not exceed 93% or below. Please reconcile.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:16:33
User opened query 'PV Query: On days 12 Dec 2020 and 15 Dec 2020, oxygenation saturation was reported to be 92%. COVID severity assessment reports the subject 's oxygenation saturation did not exceed 93% or below. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 20:29:01
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:49:45
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 20:20:20

US3442173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:43:12

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 20:20:20

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:43:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:34:59
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:19:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 18:21:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:21:48
Data point term sent to Coder	System	16 Sep 2020 18:21:06
User entered 'ozempic'	(b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'diabetes type 2'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '04 Mar 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Sep 2020 18:20:30

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: SUVOREXANT, PRODUCTSYNONYM: BELSOMRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 18:22:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 18:22:41
Data point term sent to Coder	System	16 Sep 2020 18:22:07
User entered 'belsomra'	(b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'insomnia'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'un Oct 2019'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 18:21:10

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 02:10:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 02:10:44
Data point term sent to Coder	System	16 Sep 2020 18:22:07
User entered 'aripiprazole'	(b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'depression'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '10'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'once daily (QD)'	(b) (4) (D) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 18:21:54

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Sep 2020 18:24:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:24:39
Data point term sent to Coder	System	16 Sep 2020 18:23:12
User entered 'trintellix'	(b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'depression'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 18:22:42

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 18:25:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:25:46
Data point term sent to Coder	System	16 Sep 2020 18:24:15
User entered 'rosuvastatin'	(b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'hypercholesterolemia'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (d) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 18:23:22

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:15:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 16:15:37
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	10 Nov 2020 16:14:36 10 Nov 2020 16:13:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 18:25:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 18:25:46
Data point term sent to Coder User entered 'trelegy'	System (b) (4), (b) (6)	16 Sep 2020 18:24:12 16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (D) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'copd'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:16:42
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'dosage updated' (Site from DM).		10 Nov 2020 16:13:55
User entered '100/62.5/25' reason for change: Data Entry Error		10 Nov 2020 16:13:40
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).		05 Nov 2020 04:59:01
User entered '100'		16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 17:16:44
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'corrected' (Site from DM).		10 Nov 2020 16:14:06
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error		10 Nov 2020 16:13:40
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		05 Nov 2020 04:59:33
User entered 'Oral (ORAL)'		16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 18:24:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 18:24:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 18:24:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 18:24:07
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:24:07

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:09:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:09:40
Data point term sent to Coder	System	10 Nov 2020 21:45:20
Data point term sent to Coder	System	10 Nov 2020 21:39:14
User entered 'ibuprofen'	(b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'BROKEN TOES: right 3rd and 4th'	(b) (4)	10 Nov 2020 21:44:36
reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:38:18
User entered 'broken toes'		

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '400'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Dec 2020 17:17:46
User entered 'Yes (Y)'	John Villegas (b) (4)	10 Nov 2020 21:38:18
	(b) (4)	
	(b) (4), (b) (6)	

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	02 Dec 2020 17:17:46
User entered empty.	John Villegas (b) (4)	10 Nov 2020 21:38:18
	(b) (4)	
	(b) (4), (b) (6)	

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User entered empty.	System	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User entered empty.	System	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:58
User entered empty.	System	10 Nov 2020 21:38:18

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: FLUZONE [INFLUENZA VACCINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:40:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:40:40
Data point term sent to Coder	System	10 Nov 2020 21:40:15
User entered 'fluzone'	(b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'influenza'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0.5'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User entered empty.	System	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User entered empty.	System	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:23:01
User entered empty.	System	10 Nov 2020 21:39:49

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:13:21
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' answered with 'Per Lead CRC, medication is an addition, not due to worsening of medical history condition. thank you. ' (Site from DM).	Oluwatosin Akingbala (b) (4)	31 Mar 2021 20:25:38
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DEPRESSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:11:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 00:57:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 00:57:48
Data point term sent to Coder	System	03 Mar 2021 00:56:32
User entered 'seroquel'	Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
	(b) (4)	
User entered 'No (N)'	Oluwatosin Akingbala	03 Mar 2021 00:56:31
	(b) (4)	

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'depression'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered '50'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response indicates 'updated'; However there is no update made. Please review the pre-defined options available (eg: once daily) and update as appropriate else confirm correct. Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 05:35:36
Query 'Per CDM re-query: Response indicates 'updated'; However there is no update made. Please review the pre-defined options available (eg: once daily) and update as appropriate else confirm correct. Thank you. ' answered with 'data updated' (Site from DM).	William Seger (b) (4) (b) (4)	13 Apr 2021 15:28:17
User entered 'once daily (QD)' reason for change: Data Entry Error	Alma Guel (b) (4)	07 Apr 2021 22:12:23
User opened query 'Per CDM re-query: Response indicates 'updated'; However there is no update made. Please review the pre-defined options available (eg: once daily) and update as appropriate else confirm correct. Thank you. ' (Site from DM). User closed query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'Every night '. Please review predefined options available for 'Frequency' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 22:11:58
Query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'Every night '. Please review predefined options available for 'Frequency' and confirm or update as appropriate.' answered with 'updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:17:14
User opened query 'Per CDM: 'Frequency' is 'Other' and 'If frequency is Other, specify' is entered as 'Every night '. Please review predefined options available for 'Frequency' and confirm or update as appropriate.' (Site from DM). User entered 'other (OTHER)'	Oluwatosin Akingbala (b) (4)	01 Apr 2021 11:13:50
	(b) (4), (b) (6)	31 Mar 2021 20:25:49
	(b) (4), (b) (6)	10 Mar 2021 15:17:15
	Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
	(b) (4)	
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	07 Apr 2021 22:11:58
User entered 'EVERY NIGHT' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	31 Mar 2021 20:23:23
User entered 'every night(QHS)'	Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered '23 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 22:11:58
User entered empty.	System	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 22:11:58
User entered empty.	System	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:43:12

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 22:11:58
User entered empty.	System	03 Mar 2021 00:56:31

US3442173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:43:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:12:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 18:24:39

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'USA-US017-2021-MRNA-1273-P301000007'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'William'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'Seger'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 17:45:32
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 21:35:41
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:35:41
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:35:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered '4505 Boat Club Road, Suite 400A'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'Fort Worth'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:45:32
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:35:41

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered '76135'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
Reviewed for Safety.		05 Mar 2021 20:22:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'US'	(b) (4) System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 20:22:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
	(b) (4)	
User entered '1'	System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'USA-US017-2021-MRNA-1273-P301000007'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'William'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'Seger'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:45:32
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 21:35:41
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:35:41
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:35:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered '4505 Boat Club Road, Suite 400A'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'Fort Worth'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:45:32
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:35:41

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered '76135'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
Reviewed for Safety.		05 Mar 2021 20:22:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'US'	(b) (4) System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 20:22:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
	(b) (4)	
User entered '1'	System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered '25/Jan/2021 23:58'	(b) (4) System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
Reviewed for Safety.		05 Mar 2021 20:22:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'l'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'USA-US017-2021-MRNA-1273-P301000007'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'No (N)'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'William'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'Seger'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 17:45:32
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 21:35:41
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 21:35:41
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 21:35:41
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered '4505 Boat Club Road, Suite 400A'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered 'Fort Worth'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:28:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:45:32
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:35:41

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 23:58:40
User entered '76135'	System	25 Jan 2021 23:58:15

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
Reviewed for Safety.		05 Mar 2021 20:22:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
User entered 'US'	(b) (4) System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:12

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 20:22:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 19:13:01
	(b) (4)	
User entered '1'	System	25 Jan 2021 23:58:47

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:12

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered '05/Mar/2021 15:22'	(b) (4) System	05 Mar 2021 20:22:33

US3442173

Folder: SAE USA-US017-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:12

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:45:32
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:46:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 20:22:33